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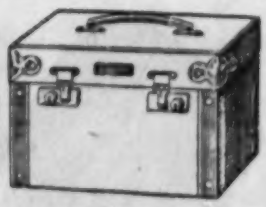

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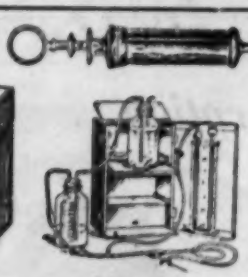

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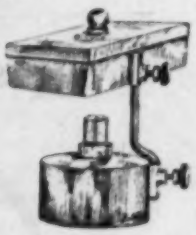

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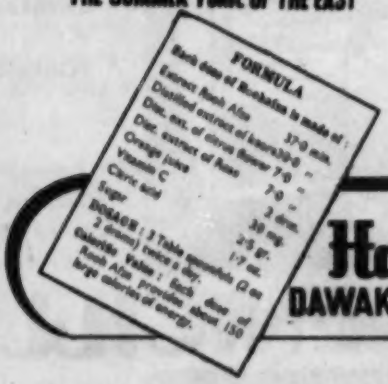
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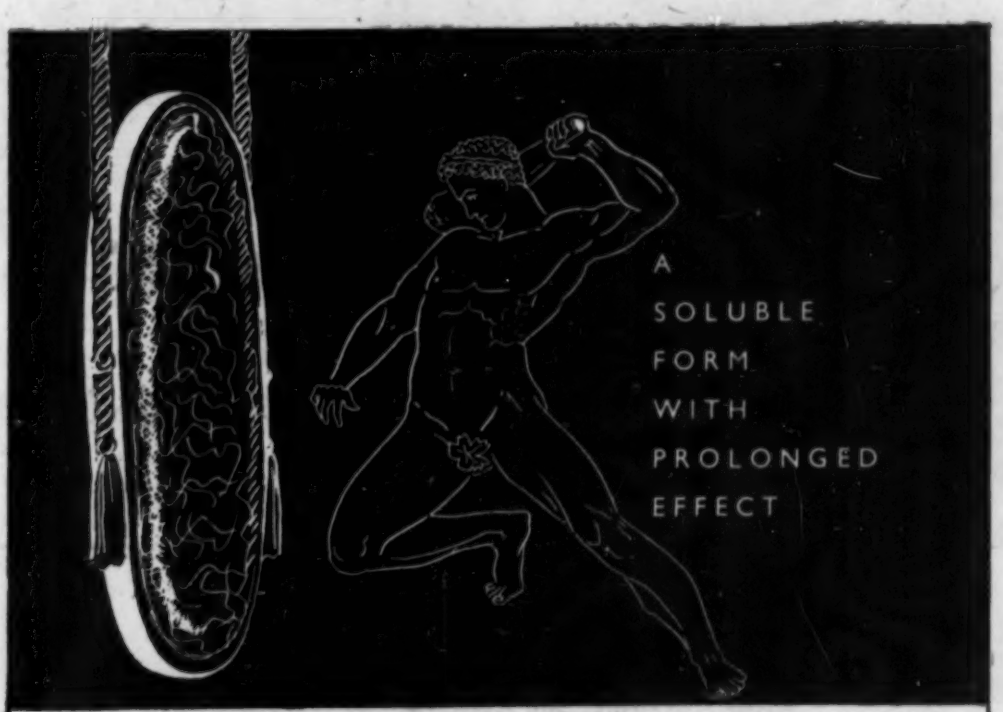

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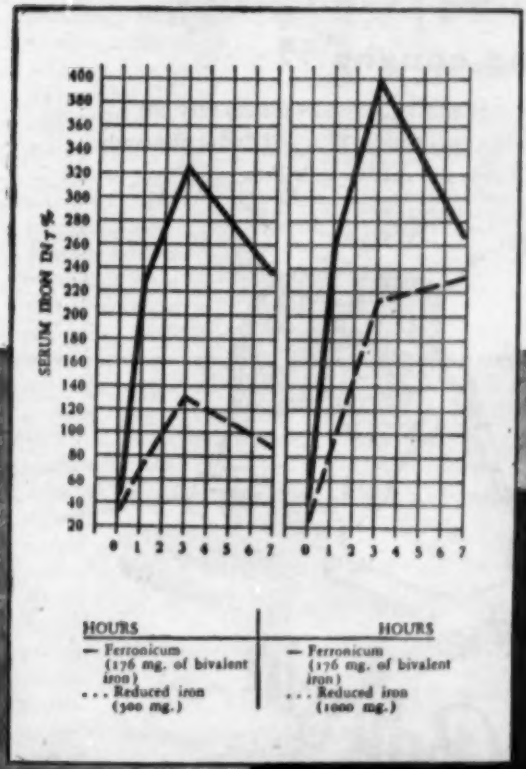

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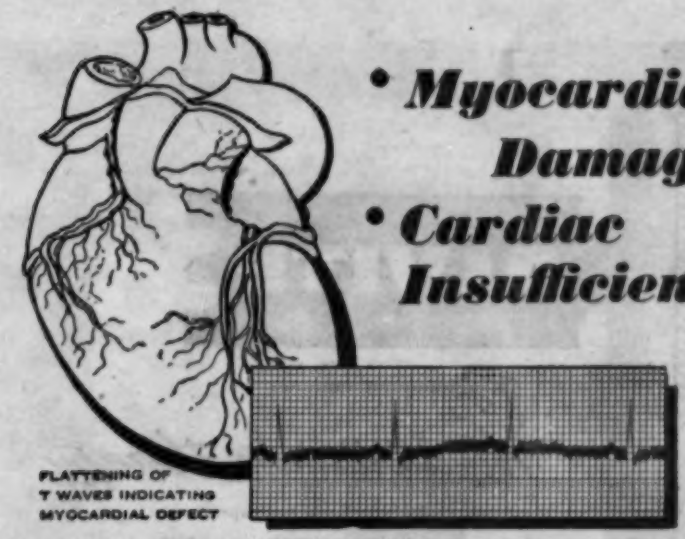

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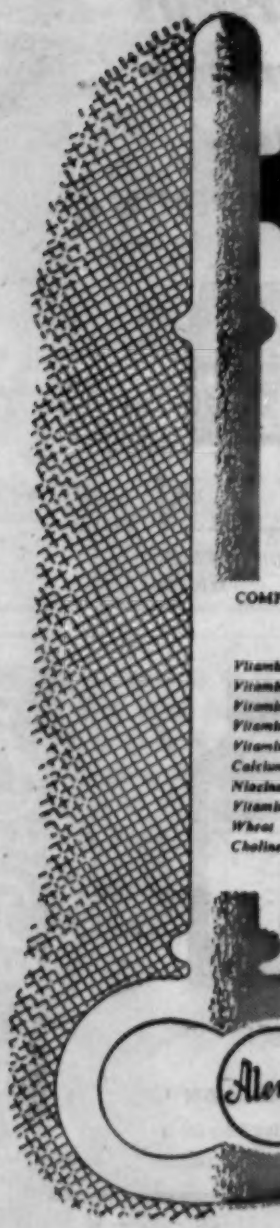

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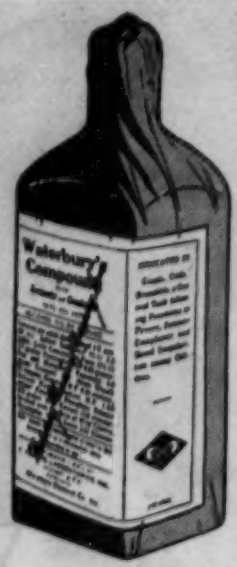

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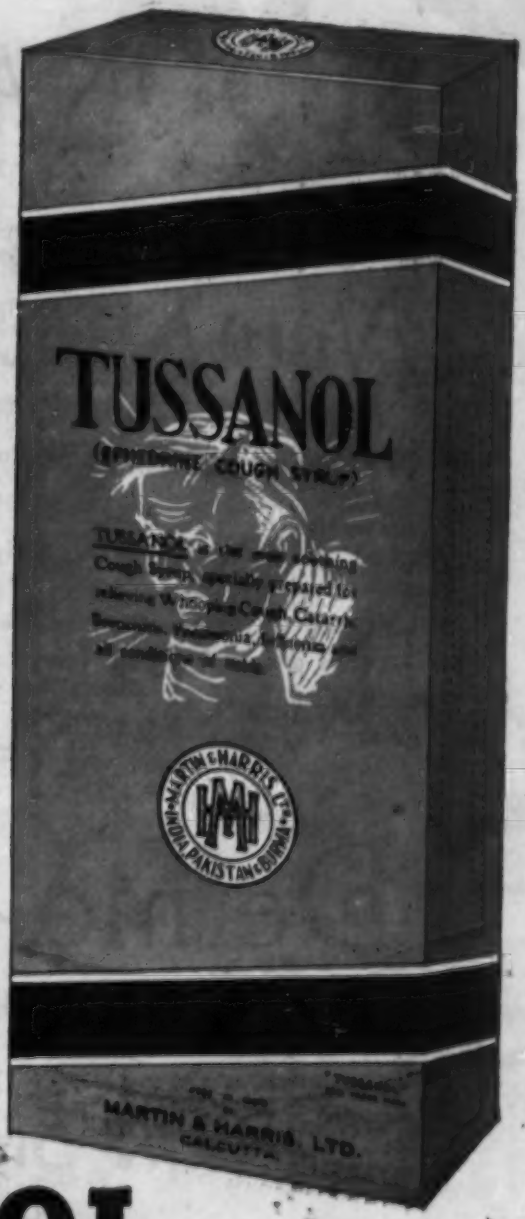

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Journal of the Indian Medical Association

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ORIGINAL ARTICLES

CARCINOMA PROSTATE — A HISTOPATHOLOGICAL STUDY

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Though carcinoma of the prostate is now no longer considered to be a rare disease, a study of literature reveals considerable difference of opinion regarding incidence, histopathological patterns and its relation to benign hypertrophy of prostate. In the present paper, a study of the material submitted to this Department after surgical removal of prostates during the 6 years (1949 to 1954), has been made with a view to investigate the incidence and to study the various histopathological patterns.

Method and Material

Our material consisted of 187 specimens of either whole prostate gland or pieces of tissue removed at operation. For histological study all the tissues were fixed in 10 per cent formol-saline and sections were cut at 4 to 6 μ after usual paraffin embedding. The sections were stained with Harris haematoxylin and eosin and Weigert's iron haematoxylin and van Gieson's stain for fibrous tissue.

Results

Histological study of 187 prostates showed the following lesions:

Benign hypertrophy	...	155 cases
Carcinoma ...	...	20 cases
Leiomyoma ...	...	12 cases

The duration of illness in these cases was variable and clinically the patients were admitted to the hospital with the complaints of either retention of urine or difficulty in micturition. Some of the patients gave history of haematuria and had developed cystitis.

The age incidence of the cases is given in Table 1. Our findings show that the maximum incidence of benign hyperplasia of prostate is during the age group 45 to 70 years though sporadic cases are observed at earlier age groups; the youngest case being in a man aged 20 years. The incidence of carcinoma is high between the age group 50 to 70 years and the youngest

Table 1—Shows Incidence of Lesions in 187 Prostate Glands

Age in years	Lesions		
	Carcinoma	Benign Hypertrophy	Leiomyoma
20—30	... nil	1	nil
31—40	... 1	1	2
41—50	... 3	24	2
51—60	... 7	70	5
61—70	... 7	46	2
71—80	... 2	11	1
81—90	... nil	2	nil
	20	155	12

case in this series was in a man aged 40 years. Leiomyoma of prostate occurred at a slightly younger age group, the maximum incidence being between 40 to 60 years.

A study of 20 prostates showing carcinoma revealed the following histological patterns: (*i*) Adenocarcinoma (15 cases), (*ii*) Spheroidal cell carcinoma (4 cases) and (*iii*) Scirrhus carcinoma (1 case).

In three of these tumours, carcinoma was associated with benign hypertrophy. In one case the carcinomatous area was distinct from the portion of gland showing benign hypertrophy while in the remaining two cases groups of cancer cells were seen infiltrating into the stroma of the gland showing hypertrophy. In none of these cases, however, a transition of carcinoma cells to hypertrophied glandular acini could be traced (Fig. 1, *vide* Plate).

Adenocarcinoma—Histologically tumours in this group showed more or less similar appearances. The normal pattern of the gland was replaced by irregular proliferated acini of prostate gland surrounded by fibromuscular tissue (Fig. 2, *vide* Plate). The acini were small, round or ovoid, in shape. They were lined by a single or sometimes two layers of rounded or cuboidal cells having prominent darkly staining nuclei and scanty pale staining, vacuolated or transparant cytoplasm. The acini showed variation in their size and shape and some of them did not have any basement cell lining or lamina propria. At places proliferated epithelial cells were arranged in solid groups, cords and sheets and were seen infiltrating the fibromuscular stroma of the gland. In addition to this pattern, 5 tumours contained large acini with evidence of intra-acinar proliferation of cells and a tendency to form small acini within the lumen of the main bigger acinus (Fig. 3, *vide* Plate). In some of the distended acini this proliferation of smaller acini gave resemblance to cribriform carcinoma (Muir, 1941) in breast and adenocarcinoma of prostate (Andrews, 1949).

Varying amount of concentric eosinophilic secretion was present in some of the acini. In 5 cases, acini showed papilliferous projections of proliferated epithelial cells inside the lumina. These papilliferous processes showed stratification of cells at places and were devoid of fibrous core which is encountered in the papilliferous projections of proliferated acini of benign hypertrophy. Evidence of stratification was seen in most of the proliferated acini, while in some cases the stratification was of transitional cell type, in others it consisted of proliferated two or more layered spheroidal cells.

Spheroidal cell cancer—Histological study of tumours in this group revealed complete destruction of normal pattern of the gland. The tumours were characterised by marked cellularity and showed infiltration of fibromuscular stroma of the gland by groups, sheets and cords of proliferated epithelial cells. Acini were absent or inconspicuous (Fig. 7, *vide* Plate). The tumour cells were round, oval or polyhedral in shape with prominent darkly staining vesicular nuclei and abundant eosinophilic cytoplasm. A number of mitotic figures and stray tumour giant cells were evident within the proliferated epithelial masses.

Scirrhus carcinoma—The normal pattern of the prostate gland was completely destroyed. It was replaced by small groups of isolated acini embedded in large amount of fibromuscular stroma (Fig. 4, *vide* Plate). These acini were lined by single layer of cuboidal epithelium with densely staining nuclei and scanty cytoplasm. At other places small groups, sheets or isolated epithelial cells were seen infiltrating inside the fibromuscular stroma. The cells were elongated or ovoid in shape with prominent vesicular nuclei and acidophilic cytoplasm.

A study of sections from the 20 tumours showed presence of tumour emboli in perineural lymphatics in four cases (Fig. 5, *vide* Plate) and inside veins in two cases (Fig. 6, *vide* Plate).

Discussion

Carcinoma of the prostate is said to be rare before the age of 50 years but its incidence rises in subsequent decades (Anderson 1953). Rich (1935) on the basis of single slide studies on material obtained from 292 autopsies found an incidence of 14 per cent for carcinoma of prostate in men over 50 years. Myers (1937) reported an incidence of 29·4 per cent in tissue removed at prostatectomy. Moore (1935) studied prostate glands removed from 229 men over 50 years and found cancer in 20·5 per cent cases, but in an over-all series of men ranging from 21 to 90 years, the incidence was 16·7 per cent. Muir (1934) gives an incidence of 16 per cent in men over 60 years; Kahler (1939) an incidence of 17 per cent in men over 50 and Baron and Angrist (1941), 47 per cent in men over 50 years. Cooray (1944) found 50 carcinomas of prostate in 897 carcinoma biopsies in males. The findings of Baron and Angrist (1941) are of interest. By examining random sections taken from prostates of 364 men over 50 years of age they found incidence of carcinoma prostate as 14·8 per cent but in another series of cases in which multiple sections were studied from the entire prostate glands of 50 unselected autopsies

on men past 50 years, carcinoma was found in 46 per cent of glands examined. In the latter group, prostatic cancer was not detected clinically, metastases were absent and carcinoma was not the cause of death. Baron and Angrist (1941) have termed these tumours as "occult" carcinomas of prostate. Similar observations have been made by Andrews (1949). Their finding have been criticised by Willis (1953) who does not agree that the incidence of prostatic cancers is as high as Baron and Angrist (1941) would make us believe.

These divergent opinions regarding incidence of carcinoma prostate are perhaps due to several causes. The methods used by workers have been different, some have based their results on single slide study while others have studied the entire glands. There is evidence that calculations on material removed at prostatectomy give a lower figure than from a study of whole gland removed at autopsy, for carcinoma of prostate is slow growing, many of these tumours are small and can be missed on gross study and that the disease is often symptomless. The incidence of carcinoma prostate, therefore, would appear higher to the pathologist than to the clinician. In the present study of 187 glands studied from age groups varying from 20 years to 88 years, carcinoma was found in 20 cases, an incidence of 10·6 per cent. Our figures are thus lower than those reported by Moore (1935) and Myers (1937). Histological differentiation between benign hypertrophy and carcinoma is not always easy and it is possible that the high incidences reported by some workers are due to the criteria used for the diagnosis of carcinoma. There is general agreement among workers that cytological evidences of malignancy are usually not well marked in prostate cancers and hence one has to mainly rely on the general pattern of the proliferated glandular acini and their relation to the stroma. Baron and Angrist (1941) and Andrews (1949) found that diagnosis could best be made with the low power objective of the microscope for then the relationship of the carcinomatous tissue could be seen with its inherent histologic rather than cytologic disorientation. Andrews (1949) states that malignant acini are small, irregular and lack lamina propria. Occasionally arrangements of proliferated epithelium in a cribriform or a solid fashion within the distended glandular acini and the cellular details are of help in the diagnosis (Totten and Stout, 1953). But diagnosis is easy when perineural lymphatic spread can be demonstrated. Moore (1935), Andrews (1949) and Kahler (1939) stress that perineural lymph spread of tumour cells is very common and when demonstrated settles the diagnosis between benign and malignant lesions. Careful search, therefore, should be made for this and also for the presence of tumour emboli in veins. In our series of 20 cases perineural lymphatic spread was present in four cases and tumour emboli in veins in 2 cases.

The commonest histologic type of carcinoma in the prostate is adenocarcinoma which has been classified into several subtypes according to degree of malignancy (Kahler, 1939; Willis, 1953; and others). Most of the tumours are characterised by small acini lined by clear cells, some are composed of large acini filled with tumour cells which are arranged in a cribriform fashion. In rapidly growing tumours anaplasia is evident and cells are distributed either as small solid masses or form ill-defined irregular acini (spheroidal cell or scirrhus type of carcinoma). A less frequent type of carcinoma of prostate is the squamous celled type. In the present study all the carcinomas were columnar celled and no example of the latter was observed.

Controversy still exists between the relationship of coexisting pathological lesions in prostate and carcinoma particularly to benign hypertrophy. While some workers believe that benign hypertrophy is a precancerous condition (Ewing, 1942. Alberran and Halle 1900, Moore 1935, Andrews, 1949), other workers think that these two conditions have no relationship with each other (Muir 1934, Kahler 1939). The view that benign hypertrophy of prostate is a precancerous lesion is based on the close similarity in the age incidences of the two lesions, their frequent coexistence in a number of cases and their relationship to endocrine influences. Anderson (1953) states that 15 to 20 per cent of hyperplastic nodular prostates show carcinoma and that 50 per cent of prostatic cancers are associated with nodular hyperplasia. Andrews (1949) believes that benign hypertrophy and carcinoma are closely related. Albarran and Halle (1900) found that a careful study of enlarged prostates revealed early cancerous changes in 10 per cent. The opposing view that there is no causal relationship between benign hypertrophy and carcinoma is based on the evidence that prostatic carcinoma arises in that portion of the gland viz., the posterior lobe, which is free from involvement in benign hypertrophy. Baron and Angrist (1941) found that whenever carcinoma was present in hyperplastic glands, it occurred in the intervening atrophic areas of the gland and not in the adenomatous nodules. The controversy is difficult to settle with the present state of our knowledge and requires further study. In our series, coexistent benign hypertrophy and carcinoma were found in 3 out of 20 cases examined. As material in this study consisted of tissues re-

moved at operation it was not possible to determine whether carcinoma arose in the posterior lobe or otherwise. Histologically, however, both these lesions were found to be discrete and no areas where origin of malignancy could be traced to benign hypertrophied acini could be discerned. At some places adenocarcinomatous acini were seen lying side by side and often in between the acini of benign hypertrophy which we interpreted as due to invasion by tumour cells. A close relationship between the two lesions, however, cannot be altogether denied unless a serial section study of an adequate material is carried out.

Summary

(1) Histopathological study of 187 prostates removed at operation has been carried out with a view to find the incidence of carcinoma and the histological patterns.

(2) Carcinoma was found in 20 out of 187 prostate glands studied. Thus, cancer accounted for 10·6 per cent of all enlarged prostates in the present series.

(3) Study of 20 prostate cancers showed the following histological patterns: Adenocarcinoma—15 cases; Spheroidal cell carcinoma—4 cases; Scirrhus carcinoma—1 case.

(4) In 3 cases, carcinoma occurred in glands showing benign hypertrophy, but histological study did not reveal any evidence of origin of carcinoma from hypertrophied acini. Both these lesions appeared to be separate and distinct.

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SOME OBSERVATIONS ON THE SIGNIFICANCE OF TUBERCULIN TEST DURING INFANCY AND EARLY CHILDHOOD

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In infancy and childhood, when the chances of infection are very remote because of a very limited field of activity, a small percentage of children show evidence of infection in the form of tuberculin positivity. Once a primary lesion develops, it takes from 6 months to 2 years for its complete retrogression and healing. Much significance is, therefore, attached to the tuberculin test in these cases and active lesion may tentatively be diagnosed on the assessment of the tuberculin test alone. It is on this basis, that a child upto 6 years of age, who shows positive reactions on tuberculin test, is considered to have an active tuberculous lesion and is subjected to a detailed and thorough examination in this centre as in other places. The primary objective of this article is to evaluate the significance of the tuberculin positivity in infancy and early childhood and to see how far one is justified in the aforesaid assumption.

Material and Method

The series of cases under the present study belong to the period from December 1, 1953 to April 30, 1954. Children upto the age of 6 years, who attended T.B. Centre, Patna during the period numbered 631. 5 T.U. tuberculin was given intradermally to all and they were directed to report for assessment of result on the 4th day. 398 (62·9 per cent) turned up and the tuberculin test result was assessed. This comprises the material of the present work.

With the arrival of a child a standard examination card was prepared in the centre for each child in which a record was made of the age, sex, residence (whether rural or urban) and lastly whether he or she has been in contact with a case of pulmonary tuberculosis or not. The tuberculin test with 5 T.U. was next performed with intradermal technique, followed by assessment of the result on the 4th day. If induration measured 5 mm. or more, a clinical date was prepared and the child was subjected to detailed examination, which consisted of (1) History taking. (2) Physical examination with particular reference to chest. (3) Fluoroscopy. (4) X-ray. (5) Laryngeal swab culture.

(6) W.B.C. count. (7) E. S. R. estimation. Examination of sputum was done whenever it was available. If a diagnosis of pulmonary tuberculosis was arrived at, specific treatment was decided upon and carried out under frequent check-ups. Since there is dearth of indoor beds in the centre, the treatment had to be carried out at the patient's home and since many of them came from outside Patna, follow-up in many of the cases became far from adequate. In case of doubtful diagnosis the child was kept under fortnightly or monthly observation without any treatment and the diagnosis was arrived at in due course. In cases where no other cause was obviously discernible and there was strong reason to suspect the disease, a therapeutic trial of the specific remedy was envisaged and a conclusive diagnosis was left for a later date. The criteria of diagnosis have been mostly a combination of factors such as history, symptomatology and the results of the various investigations performed including of course the therapeutic response rather than on one single factor alone of whatever significance or import.

Results

Of the 398 cases under observation, 151 cases showed positive tuberculin reaction (57·2 per cent). Amongst these positive reactors who were subsequently subjected to further investigations, 56 cases turned out to have active tuberculous lesions based on skiagraphic finding in all of them and supported by history and symptomatology (46 cases) and/or by therapeutic response (51 cases), to the specific treatment. Only 5 of these cases were bacteriologically positive.

Age distribution—This is given in Table 1.

Table 1—Showing Age Distribution

Age Group	No. of children attended	No. of children who showed positive tuberculin test	No. of children who showed positive evidence of tuberculosis
0—1 ...	52	10 (19·4%)	3 (30%)
1—2 ...	73	21 (28·8%)	10 (47·6%)
2—3 ...	62	26 (41·9%)	14 (53·8%)
3—4 ...	68	29 (42·6%)	13 (44·9%)
4—5 ...	82	40 (48·7%)	11 (27·5%)
5—6 ...	61	25 (41·5%)	5 (20%)
Total ...	398	151	56

Sex—Of the total of 398 cases, 229 were male (57 per cent) and 169 female children (43 per cent). Of the 56 who had active lesion, 29 were male and 27 female.

Locality—163 children came from rural area and the rest from urban residence.

History of contact—83 of the total and 16 of the positive reactor and 10 of the active disease group gave history of contact.

Tuberculin reaction—Among the positive reactors tuberculin test reading varied between 6 mm. and 20 mm. with an average of 12·9 mm. But 56 cases of active disease showed a mean reading of 11·3 mm. as against 13·7 mm. in the other group.

Radiological findings—The skiagraphic findings in 56 cases could be classified as follows:

Primary complex ..	..	24 cases
Disseminated tuberculosis ..	2	,,
Bronchogenic phthisis ..	30	,,

The lesion in the last type, comprised of unilateral infiltrations or consolidation in 18 cases, bilateral infiltrative lesions in 8 cases and unilateral lesion with cavity in 4 cases. Three cases with cavity showed either positive sputum or laryngeal swab culture. Two of the lesions with consolidation showed positive laryngeal swab culture.

Discussion

Tuberculin positive reaction—The tuberculin skin test result was positive on the average in 37·9 per cent of children. The percentage is obviously very high. The usual percentage mentioned for the age of 5 years is 20 per cent for the maximum. This high incidence of Mantoux positivity is explained by the fact that the group population under investigation does not represent a survey work in any locality but comprises of those who came to the centre from various places. On the other hand, this group comprises of children who came to the centre with some chest symptoms or were contacts of established cases of tuberculosis. None the less, such high incidence of Mantoux positivity in infants and children under 6 years of age does indicate a fairly high incidence of tuberculous disease in active phase in the community.

The study of the age distribution (Table 1) reveals the following: A. The age distribution shows two peaks, the first at the age of 2 years and the second at the age of 5 years and there is a fall in the attendance at the age of 6. The fall in attendance at the age of 6 is justified since the golden age period in tuberculosis is 6th to 10th year. The vast majority of sufferers in the

group 2-5 years with more or less rising curve is in conformity with progressive Mantoux curve with the advance of age.

B. The above figures clearly show that with the advance of age there is progressive increase in the percentage of tuberculin positivity (with the possible exception of the last age group). The positivity has increased from 19·4 per cent at the age group under 1 year to the maximum of 48·7 per cent at the age of 5 years. With the advance of age there is gradually an increased chance of coming in contact with a case of tuberculosis and therefore progressive increase in percentage of tuberculin positivity with ethe advance of age is but natural.

C. There has been progressive increase from 30 per cent upto the age of 1 to 53·8 per cent at the age of 2-3 years and then it shows progressive decline so that it is 20 per cent at 6 years. Thus it is evident that in infancy and early childhood children fall a comparatively easy prey to the disease process and with the further advance in age the morbidity decreases, till by the age of 6 years when the child enters the golden age period, the morbidity is minimum.

There does not appear to be any appreciable discrimination for sex in tuberculous infection or disease during infancy and early childhood when the environmental condition and chances of infection are more or less alike.

163 children came from rural and 235 from the urban residence. The higher attendance from the urban residence is due to better transport facilities, increased publicity and higher level of consciousness. Rural population showed a tuberculin positivity of 52·1 per cent whereas the urban population showed only 28 per cent positivity the most probable underlying factor being that the rural children came mainly from healthy families. This explanation is borne out by a higher morbidity rate in rural group. Out of 163 from the rural areas 27 (16·7 per cent) were diagnosed to have definite positive findings whereas out of 235 from the urban area only 29 (12·3 per cent) had demonstrable lesion. The higher morbidity among the rural attendance cannot justifiably mean higher morbidity rate in the rural population. It is only because of the fact that most of the children from rural area came only when they had some definite indications of illness or were intimate contacts of some positive cases of tuberculosis in the family whereas in the town, even healthy children came for examination because of better transport facilities or because of higher consciousness for such examination in the town.

History of having been in contact with a tuberculous patient could be established in 83 cases with some amount of certainty. Remaining 315 denied any clear history of such contact. Among 83 contacts only 16 showed positive reaction (19·3 per cent). Amongst the non-contact children 135 showed positive reaction (43 per cent). Out of 83 only 10 (12 per cent) cases proved to have obvious lesion. Thus there does not appear to be any marked influence of 'contact' on the incidence of disease. As a matter of fact morbidity has been less in the contact series of the present work. The probable factors which are responsible for such unusual figures may be:

(1) The incidence of tuberculosis is very high and the number of unexplored cases is fairly huge in comparison to those already known to us.

(2) These unexplored cases are more potent sources of infection and disease than the explored ones. Since there is no knowledge of these unexplored cases in our country, our contact determination is fallacious. This higher morbidity figure in the so-called non-contact group may reasonably be taken to point out that there are many unstamped cases of tuberculosis in this group also.

There is no denying the fact that disease develops only in those who are infected and in whom Mantoux test is positive i.e., infection *per se* does never play any dominant role in the development of the disease process of bronchogenic phthisis. The factor operating is something else, and which goes by the name of individual resistance.

Significance of the Dimension of Tuberculin Reaction

The measurement among the positive reactors varied between 6 mm. and 20 mm. for the transverse diameter, the average mean being 12·9 mm. Although no clear-cut demarcation is laid between a 'low positivity' and a 'high positivity' we shall call 'high reaction' to one in which the transverse diameter of induration measures 10 mm. or more. With such criterion, the 'high type reaction' occurred in 110 or 78·8 per cent of cases. If we analyse 56 diagnosed cases, which showed some demonstrable lesion, reaction measured from 6 to 20 mm. with the average mean of 11·3 mm. The high type reaction was recorded in 44 i.e., 78·6 per cent of cases. Thus there does not appear to be any definite co-relation between the size of reaction and the tuberculous lesion. In other words, there is no justification in assuming a lesion if the reaction has been severe. Apart from these, not infrequently cases of definite bronchogenic phthisis could be diagnosed where the reaction has measured as low as 6 mm. and in

many instances not even a trace of any lesion could be demonstrated with equal frequency when the reaction measured 20 mm. or more with vesicles. Thus the size of the reaction leads us to nowhere. Multiple factors operate and are jointly responsible for the size of the reaction and probably nothing can be justifiably inferred from the size of the reaction so far as the disease or lesion of tuberculosis is concerned.

It is true that the vast majority (78·6 per cent) of cases diagnosed have shown 'high type reactions but not much less figure (63 per cent) is for those who had high type reaction yet did not show any demonstrable lesion. The incidence of tuberculin positive reaction 'high type' showed no lesion in a fairly clear-cut majority of cases (63 per cent). In this group, the positive reaction means infection only without any lesion of skiagraphic dimensions or in a state to give positive bacteriological finding. In these 75 cases (63 per cent) infection occurred but neither disease nor its footprints could be seen except the altered body reaction in the shape of tuberculin positivity. As such one is wholly justified if Mantoux positivity is taken for infection only even in infancy and early childhood. One is also justified in inferring that in a large percentage of cases, infection of tuberculosis is more or less benign and leaves little other than manifestable positive tuberculin reaction.

Summary

1. The tuberculin positivity, on the average, was 37·9 per cent and morbidity was 14·06 per cent for children upto the age of 6 years in a group of 398 cases.

2. The investigation shows progressive increase in the percentage of tuberculin positivity with the advance of age, with the maximum at the age group 4-5.

3. Demonstrable lesion could be shown in gradually increasing percentage from under 1 to 3 years with the maximum at the age group of 2-3 years. Gradual decline in percentage curve was manifest for the age of 4 to 6 years.

4. The two sexes showed little difference in the percentage of tuberculin positivity as also in the development of disease process.

5. History of the so-called contact does not appear to have any marked obvious effect on the development of disease process.

6. The positive tuberculin reaction undoubtedly means infection with tubercle bacillus (with some insignificant limitations) but it does not mean active disease even in infancy and childhood. In the vast majority of cases tuberculous infection occurs almost quite silently and is more or less a benign affair and tuberculin positivity is the only manifestable evidence left.

7. 37·8 per cent of positive reactors showed active demonstrable lesion which is quite sufficient to warrant a thorough investigation in all the tuberculin positive children, more so in the group of children having some symptoms referable to chest or of a toxic nature.

8. The size of the tuberculin reaction is not helpful in diagnosing tuberculosis. The role of 'high type' and 'low type' reaction is not distinctive.

GASTROPTOSIS

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Gastroptosis means an abnormal and a permanent downward displacement of the stomach. The exact diagnosis of gastroptosis is made by an x-ray examination in standing position after a barium meal. The examination is repeated after 6 hours to see any stasis in the stomach.

The recognised causes of ptosis are: (*a*) The reduced tone and weakness of the abdominal and pelvic muscles, which leads to a fall in the intra-abdominal pressure and so the viscera lose their normal position and tend to fall downwards by gravity. The hypotonia and weakness of abdominal and pelvic muscles are due to stretching of these muscles during pregnancy. After confinement there is a considerable fall in the intra-abdominal pressure due to the laxity of the muscles. But if a woman takes enough rest in bed and a well-balanced diet, the muscles slowly regain their tone. But with insufficient rest and a poor diet the muscles remain permanently weak. (*b*) In neurasthenic individuals whose nervous system, especially the autonomic, is unstable and irritable, hypotonia of muscles of the digestive tract is quite common.

Materials for Study

A record of 38 cases seen at Sir Takhtasinhji Hospital, Bhavnagar, Saurashtra is reported below:

This includes 15 males and 23 females and the age of the patients ranged from 23-50 years. 18 patients were from Bhavnagar City and 20 from the nearby villages. 22 of the 23 female patients had each given birth to 5 or more children. 19 such multiparous patients admitted that they could not take sufficient rest after confinement due to social or economic reasons. 9 female patients gave past history of dysentery or diarrhoea. 3 out of these 9 patients had repeated attacks of diarrhoea. In 2 female patients, without any history of dysentery

or diarrhoea, cysts of *Entamoeba histolytica* were detected. 4 male patients and 1 female patient, who was married for a long time but had no child, were neurasthenic and had typical hyposthenic build. 9 male patients gave history of dysentery or diarrhoea. 2 male patients had associated pulmonary tuberculosis.

Symptoms and Signs

Pain in the abdomen—This symptom was present in all cases. Its commonest site was epigastric and umbilical regions. In 13 patients pain was present throughout the day. But in the majority of patients pain was present for a few hours only after meals and on assuming erect posture. Pain was severe in 8 cases, moderate in 15 cases, and mild in 15 cases. Pain was colicky in nature in 15 patients.

Symptoms and signs	*No. of cases*
Reduced appetite	22
Loss of appetite	9
Vomiting	13
Constipation	20
Headache	12
Flatulence	32
Discomfort immediately after a meal. This discomfort afterwards assumed the form of actual pain.	24
Neurosis	15
Emaciation	13
Undernutrition	25
Signs of vitamin B deficiency	28
Pallor	22
Scaphoid shape of abdomen	20
Lax abdominal muscles	30

Loss of weight, weakness and tiredness and vague generalised abdominal tenderness were present in all the cases.

Diagnosis

In every patient with pain in the abdomen, a routine fluoroscopy examination with barium meal was done. Criteria for radiological diagnosis of hypotonic stomach were taken as follows:

"Stomach has a J or fish-hook shape. The greater curvature at the lower pole tends to sag down, making the lumen larger than elsewhere. The lumen of *pars media* collapses from complete filling and dragging. The most dependent portion of the greater curve may reach half way between the umbilicus and the symphysis pubis (Text book of Radiology by British authors)."

All the cases of gastroptosis had an associated ptosis of the duodenum. In 8 cases there was ptosis of the transverse colon, in one ptosis of the entire colon, in one of ascending colon, which was further confirmed by an examination with barium enema. In every case of pain in the abdomen a stool examination was also made, if necessary, after giving a saline purge. In 20 cases, stool examination revealed the presence of cysts of *E. histolytica*. Gastric analysis was done in 21 patients. There was hypochlorhydria in 3, 18 showing normal values.

Management

In those cases showing cyst of *E. histolytica* in the stool antiamoebic drugs produced marked relief in pain, flatulence, vomiting and improved their appetite. Patients were strictly confined to bed, with the foot-end of the bed raised by wooden blocks, during their stay in hospital. Abdominal massage was done twice a day and subsequently a tight abdominal binder applied. Patients were given small feeds several times a day and they were told to lie on their right side for about an hour after every meal. Tonics, multivitamin preparations and anti-anaemic drugs were also given. Neurasthenic patients were put on sedatives also. Reassurance, a sympathetic attitude and encouragement towards these patients went a long way in obtaining their co-operation in the treatment and also in improving their condition. The treatment was found exhaustive both for the patients and the medical staff. The results of the treatment were quite satisfactory in 20 patients suffering from amoebiasis, but far from satisfactory in 5 neurasthenics. The remaining 13 patients were discharged with a moderate relief in their symptoms.

Comments

Gastroptosis does not seem to be so uncommon in Bhavnagar. Repeated pregnancies, undernutrition and insufficient rest after deliveries play a major part in the causation of the disease in women. The study of these 38 cases reveals that more than 50 per cent had chronic amoebiasis. Amoebic infection is widely prevalent in Bhavnagar. Chronic amoebiasis is rather difficult to cure, and the chronicity of the disease makes the patient suffer and worry a lot producing an anxiety state and neurasthenia. This neurasthenia plus the chronic inflammatory changes in the colon may lead to hypotonia of the muscles of the stomach and colon and subsequent ptosis. So it appears, chronic amoebiasis may also be an important factor in the pathogenesis of this disease. In each and every case of abdominal pain, routine stool examination should be done, repeatedly, if necessary, to exclude chronic amoebiasis as also a barium meal examination to obtain useful information regarding the vague symptoms.

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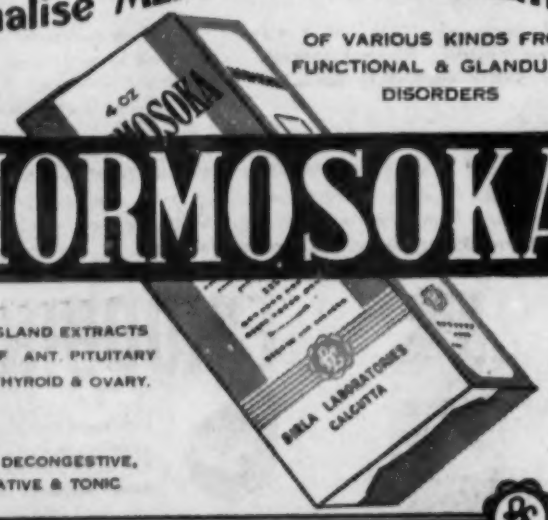

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ANTIVIRAL IMMUNITY

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It is a remarkable feature of many of the virus diseases that they lead to a highly effective and lasting specific immunity. For instance, virus diseases like smallpox, measles, poliomyelitis, and yellow fever may produce even lifelong immunity in those who have recovered from these diseases. On the other hand, numerous examples can be cited among the virus infections in which the post-infection immunity is of short duration. Well-known examples are common cold and herpes febrilis. Too much emphasis should not, therefore, be put on the long duration of antiviral immunity as a point of difference from antibacterial immunity.

Indeed, the serological phenomena of immunity to virus diseases are essentially similar to those of bacterial infections. Thus, specific antibodies can be demonstrated in the serum of convalescents from virus diseases just as they could be demonstrated in convalescents from bacterial infections. These antibodies show *in vitro* reactions such as precipitation and complement fixation with virus-containing material. Where it is possible to separate, concentrate, and purify the elementary bodies of a virus, and prepare a suspension of these elementary bodies, agglutination tests could be performed with these suspensions and the patient's antiserum, just as similar tests are done with bacterial suspensions and the patient's serum. An antiserum inactivates the specific virus in the same way as antitoxins neutralise the specific toxins. Even in the matter of absorption of the specific antibody in an antiviral serum with a suspension of elementary bodies, there is close resemblance with bacterial antigen-antibody reactions.

Artificial immunity to virus infections can be produced by parenteral administration of living attenuated viruses, or killed viruses, just as artificial antibacterial immunity can be produced with living attenuated or killed bacteria. The mechanism of antiviral and antibacterial immunity appears, therefore, to be one and the same.

Natural Active Antiviral Immunity

Evidence of development of active natural immunity appears after recovery from many different virus infections. Several virus diseases, such as smallpox, chicken-pox, measles, mumps, poliomyelitis, yellow fever, etc., are followed by development of firm active immunity after recovery from infection.

Development of lifelong immunity after recovery from smallpox was such a common knowledge that "in pre-vaccination days in England, as in other countries, men declined to marry maidens who had not had smallpox, lest they developed the disease after marriage". It has indeed been observed in several outbreaks of smallpox that those who escaped infection were persons who had had smallpox previously. It has also been known for a long time that on recovery from vaccinial infection experimental animals become immune to re-infection.

Recovery from varicella (chicken-pox) is also associated with a solid immunity to re-infection in almost all cases. A few, however, get second attacks, but their proportion seldom exceeds 1 per cent of those involved in any outbreak.

Similarly, an attack of *herpes zoster* (shingles) is generally regarded as giving lifelong immunity against further recurrence. However, as in the case of varicella so also in the case of herpes zoster a few do get second attacks.

It is generally believed that herpes zoster seldom occurs in cases that have had varicella, and *vice versa*. Or, in other words, a cross-immunity develops out of varicella or herpeszoster infection. This belief, however, is not supported by several carefully collected field data. For instance, one such careful investigation had shown that a very large proportion of boys suffering from zoster had previously had chicken-pox. It might be due to a very short duration of the cross-immunity. However, it would be preferable to keep one's mind open regarding the belief that varicella immunises against zoster, and *vice versâ*.

Measles too ranks itself among the developers of firm natural immunity. An attack of measles usually confers a strong and lifelong immunity. Relapses are uncommon and second attacks are very rare. It is not only the disease but also latent subclinical infections which can produce immunity. However, unlike the firm immunity developing from overt infections, the immunity following latent infections is short-lived, perhaps not longer than 18 months. Nevertheless, both the overtly and the latently immunised together seem to determine the periodicity of measles epidemics. When the numbers of both of these two categories of immunes increase simultaneously the epidemic disappears. Subsequently, the latently immunised revert to their susceptibility, and newborn children swell the number of susceptibles. Con-

sequently, a fresh epidemic starts, and this cycle goes on repeating itself to constitute the periodicity of measles epidemics.

Mumps is another virus disease which also develops a firm and lasting immunity. Second attacks are extremely rare, though, of course, a few exceptions prove the rule.

Poliomyelitis can also be included in the same list. A lasting and high grade immunity follows recovery from poliomyelitis. Both relapses and second attacks are most uncommon. When, however, they do occur, it is usual for the relapse to appear within 3 months of the first attack, and the second attack any time between 2 and 16 years after the first attack. It should be repeated for the sake of emphasis that both relapse and second attack are extremely rare.

Equally lasting and more widespread is the natural immunity to *yellow fever*. The prevalence of this natural immunity has been revealed by mouse protection test for detection of yellow fever virus neutralising antibodies in human sera. Large collections of random samples of sera, submitted for test from different parts of Africa and South America, have shown presence of significant quantities of this antibody. Not only the people of the areas in which yellow fever is endemic, but also those living in areas in which clinically reported yellow fever has been absent since many years, show this antibody. These findings illustrate the prevalence of natural immunity in both endemic and "silent" areas. The latter are areas in which clinical yellow fever have ceased to occur since a long period.

This finishes the list of virus diseases which are followed by development of a lifelong, firm and active immunity. In contradistinction to these, there are other virus diseases, such as herpes febrilis, common cold, influenza, dengue, sandfly fever, etc., which are known for their short-lived immunity.

Herpes febrilis hardly ever confers any immunity to the infected, and hence recurrent attacks are very common. The vesicles, however, tend to avoid old spots and prefer newer spots for appearance, though no significant local immunity could be attributed for it.

The natural immunity to *common cold* is equally short-lived. The immunity following an attack, if it develops at all, does not seem to last longer than 3 to 7 weeks.

An attack of *influenza* develops a slightly stronger immunity. However, the immunity seldom lasts over a year, and perhaps starts waning earlier still.

Sandfly fever seems to produce a triflingly better immunity. Though repeated attacks of the disease have occasionally been observed to happen even during the same season, the immunity is generally strong enough to protect till the next season. When, however, the disease occurs in a previously attacked person, it shows itself to be a very mild and modified attack.

In comparison with these four, an attack of *dengue* seems to offer a significantly stronger immunity. When repeated attacks occur in a person, it is believed to be caused by strains which differ antigenically from those which had infected before. Generally, however, an individual, who has once suffered from the disease, remains solidly immune at least for a year or so.

Artificial Active Antiviral Immunity

Smallpox—That smallpox is preventable by vaccination is now common knowledge. The variola (smallpox) virus, when grown in the skin of calves, mutates itself to vaccinia (cow-pox) virus. Inoculation of this vaccinia virus back into the skin of a man is known as vaccination, which produces a mild disease but develops a firm immunity against smallpox.

The potency of the vaccine lymph, as well as the response of the host, determines the type of reaction to primary vaccination. Three different types of reaction may be observed during primary vaccination: (1) the classical type, (2) the accelerated vesicular type, or (3) the allergic early papular type.

The classical primary vaccination reaction consists of development, 3 days after vaccination, of a papule, which on the 5th day converts itself into a vesicle. The vesicle gradually increases and accumulates pus till on the 9th day it develops into a full-fledged pustule. From the 11th day onwards the pustule undergoes drying and forms a scab which eventually falls off leaving behind it an everlasting scar.

Revaccination with a potent lymph produces one of the 3 different types of reaction according to the state of immunity prevailing in the subject: (1) the classical reaction in fully susceptibles; (2) the accelerated reaction, which attains its peak between the 3rd and the 7th day and recedes much earlier than the classical reaction, in partially immunes; and (3) the immune reaction, which shows itself only as a red areola with or without papule appearing soon after vaccination, in fully immunes.

The protective power of vaccination against smallpox is one of the best established facts in preventive medicine. The immunity lasts at least 3 years, a period of 4-5 years may be regarded as the average duration, but the immunity often lasts

much longer. Usually, revaccination need not be more frequent than every 3 years. But those who are heavily exposed to infection, like the doctors, nurses, and attendants of the smallpox ward in a hospital, should be revaccinated every 6-12 months.

Rabies—Prevention of rabies with antirabic treatment is one of the most thrilling chapters of medical research. Satisfied with experiments in dogs, Pasteur ventured to extend his experiments to human cases of rabies. His first human case, Joseph Meister, was saved from certain death by antirabic treatment. Pasteur prepared his antirabic vaccine with *virus fixe* (fixed virus), which was a modified version of the virulent virus of rabies, the street virus. After several passages of this street virus through rabbits' brain and cord, it changed its properties and became converted to fixed virus. This fixed virus was next attenuated by drying the rabbit cord infected with the fixed virus. The longer the period of drying the more attenuated was the virus. Drying for 14 days made the virus completely safe for immunisation, though it was still living. The first dose of rabies vaccine given to Joseph Meister consisted of a suspension of this 14 days dried cord. Subsequent doses consisted of suspensions of cord dried for a progressively shorter period. He did not suffer from any ill effects, and he survived the bite of a rabid dog.

Pasteur's attenuated rabies vaccine proved its value and general safety in subsequent trials. However, occasional severe and fatal accidents were still reported. Hence, several modifications were made to improve its safety. Semple's 5 per cent carbolised sheep brain vaccine is one such modification, which is still the current method of preparation of antirabic vaccine.

Antirabic treatment develops rabicidal antibodies in the serum of the inoculated ; but this antibody does not seem to bear any direct relationship with the protection acquired. For instance, a person may be protected against rabies and yet show no rabicidal antibody, and, conversely, a person with a high antibody titre may die from rabies.

The protection offered by antirabic treatment, though very sound; is not absolute. Carefully collected statistics reveal that between 0·15 per cent and 0·63 per cent of the inoculated die of rabies. An explanation for these failures was offered principally by the severity and the position of the bite, and delay in commencement of the treatment.

Yellow fever—This is another virus disease which has been successfully prevented by active immunisation with yellow fever vaccine. A living attenuated strain 17D is used for this immunisation. A single immunising dose, containing not less than 500 mouse lethal doses, gives protection which lasts at least for 6 years.

Other virus diseases—Active immunisation against other viral diseases has not found so universal a favour as that against smallpox, rabies, and yellow fever. Influenza and poliomyelitis vaccines have received quite large-scale trials ; but there has so far been no uniformity of opinion regarding their value.

In certain large-scale trials with the influenza vaccine the results had indicated that a degree of resistance to infection had developed. On the other hand, in several other trials the inoculated persons were definitely not protected against the natural disease. Perhaps, the antigenic difference between the immunising and the infecting strains could be attributed for these failures. However, even a polyvalent vaccine, prepared with both the antigenic types A and B and 3 selected strains of the virus, has shown capricious results.

Active immunisation with poliomyelitis vaccine has also not yet received wide favour. In certain large-scale trials in the U.S.A., living attenuated viral vaccines had shown some protection. Nevertheless, the potential pathogenicity of the virus in these vaccines had fully offset the slight advantage obtained with them. However, recently renewed efforts have been made to find out a potent and safe poliomyelitis vaccine. The results have still to be waited for.

A few other virus diseases have been sought to be controlled by active immunisation. The results have not been very satisfactory. Common cold vaccine has proved itself to be useless for preventing natural attacks. Active immunisation of children by intradermal inoculation of varicella vesicle fluid has been attempted without much success. Measles virus vaccine has not shown much use. Efforts of finding a prophylactic vaccine against dengue have so far been futile. However, repeated attacks of herpes febrilis has been prevented by repeated inoculations with the patient's own vesicular fluid. And inoculations of wart material has occasionally shown to prevent future attacks.

Passive Antiviral Immunity

Natural transfer of passive immunity from mother to offspring is a regular feature of many virus diseases. The antibodies could pass from mother to child either *in utero* through the placental membrane, or with colostrum and milk to breast-fed young ones. Transfer of antibodies from immunes to susceptibles could also be made artificially. However, for prevention and treatment of virus diseases the animal-derived anti-

bodies are hardly ever useful. It is only the convalescent human serum, or pooled human gamma globulin that are likely to be of any use.

In *smallpox*, a short-lived passive immunity seems to be transferred from immunised mother to the offspring, in nature. Artificially, however, administration of immune serum simultaneous with, or a few hours later to, inoculation of variola virus seems to offer considerable protection against infection. If the immune serum were administered fairly long after inoculation of the virus, the protection would appear to be insignificant. Thus, it appears that artificial passive immunisation has more a preventive than a therapeutic value.

For controlling *chicken-pox*, *herpes zoster*, *dengue*, and *encephalitis lethargica*, passive immunisation with convalescent human serum has been attempted, but the results have not always been successful. In *pandemic influenza*, however, convalescent human serum is reported by some workers to have shown beneficial effects.

The specific immune serum can protect an exposed and susceptible person against *yellow fever* if given very early. The protection is short-lived. If, however, the virus establishes itself before administration of immune serum, even this short-lived protection is not apparent. The immune serum can, thus, only protect against infection, but is unable to cure an infection. Natural passive immunity has, however, been shown to be transferred from mother to child with the mother's milk.

In *poliomyelitis*, convalescent serum has been given in large repeated doses, administered intrathecally and intravenously, to pre-paralytic cases. From clinical observations, the serum appeared to control the disease satisfactorily. However, large well-controlled trials with this serum have failed to reveal any significant therapeutic value of this serum.

Measles, however, has shown itself to be controllable with immune serum, derived either from convalescents or normal adults. A dose of 5 ml. of convalescent serum, or 10-15 ml. of adult serum is given subcutaneously or intramuscularly early in the incubation period. In many cases the serum fully protects against the disease, in others only a mild attenuated attack occurs. Placental globulin is also as effective as convalescent serum for prevention or attenuation of measles. However, the concentrated and purified pooled gamma globulin has shown the strongest protection of all.

Indeed, *gamma globulin* has been useful not only against measles, but also against poliomyelitis and infective hepatitis.

SULPHONAMIDES

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General and Historical

For a substance to be successful in killing bacteria in circulating blood, two essential conditions must be fulfilled. It should after administration attain a concentration in blood lethal to the microbes, but at the same time be harmless to the host. When chemotherapeutic substances are injected into the blood, they may act directly on organisms to cause their death (bactericidal) or they may inhibit the growth of the bacteria (bacteriostatic), or their action may be indirect by the stimulation of the natural defensive mechanism of the tissues. All three of these factors may come into play.

The search for a specific chemical substance for the treatment of microbic infections has been conducted from the early days of bacteriology, and the first great advance in chemotherapy was the discovery of Ehrlich's Salvarsan for the treatment of syphilis. Later a number of organic compounds of arsenic and antimony were produced which were effective against protozoal and spiral organisms. But all attempts to apply chemotherapy to bacterial diseases were unsuccessful. It was, therefore, a great achievement when Domagk in 1932 found that an azo dye patented under the name of Prontosil could cure mice suffering from experimentally produced haemolytic streptococcal septicaemia. Although Galmo had first described para-amino-benzene-sulphonamide (sulphanilamide) in 1908, its antibacterial properties were not appreciated till 1935. Similarly in 1909, Horlein and co-workers prepared an azo dye containing sulphonamide and found it to be slightly effective against mouse septicaemia caused by haemolytic streptococci. Then certain other azo compounds including chrysoidine were used for chemotherapeutic purposes but without any success in infected animals. Then in 1932 came Prontosil which won Domagk the Nobel Prize. In France a similar compound called Rubiazol was prepared in 1935 and Domagk's work was confirmed. Later in England and America the previous work on para-amino-benzene-sulphonamide was confirmed and some basic contributions with regard to its pharmacology and toxicology were

made. This led to an extensive use of this compound (sulphanilamide) in the chemotherapy of a number of infections and a large number of derivatives were developed and tested. Some of these are benzyl sulphonamides. The best compound was sulphapyridine (M. & B. 693) synthesised in England. This was effective against pneumococci and meningococci etc. Since then many new compounds have appeared. Sulphathiazole and sulphamethylthiazole were introduced in 1939 and were effective against staphylococci, pneumococci and other infections. In India encouraging results were obtained against plague. Newer compounds like sulphaguanidine, sulphadiazine, sulphamerazine, etc. have been prepared which are more effective and less toxic. During recent years, a large number of sulphonamide compounds have been prepared and are being used in a number of infections. Although these compounds have been recently overshadowed by the rapidly growing popularity of the antibiotics, their reliability in certain infections is still great.

Chemistry—Para-aminobenzene sulphonamide or sulphanilamide is the simplest of all the sulphonamides and is the mother substance of the other derivatives. All these compounds contain at least one benzene ring, at least one amino or NH_2 group and one sulphonamide or amido (NH_2SO_2) group. To the opposite ends of the benzene ring are attached an amino and a sulphonamide group. The derivatives of sulphanilamide can be divided into 2 groups: Those in which the substituents are introduced in the amino group and those in which the substituents are introduced into the sulphonamide or amido group. The first group comprises sulphanilamide itself and those in which the amino group of the benzene ring is substituted by other groups. This includes prontosil (album and rubrum), proseptasine, soluseptasine and rubiazole etc. The other group includes sulphapyridine, sulphathiazole, sulphadiazine, sulphamezathine and sulphaguanidine, etc. In these, the amino group is substituted by other groups like, pyridine, thiazole, guanidine and so on.

Pharmacology

General actions—In small doses, sulphanilamide first stimulates and then depresses the central nervous system, the depression being manifested by motor paralysis and partial narcosis. Relatively small intravenous doses produce stimulation of the respiratory centre, whereas large doses produce depression and finally paralysis. The heart is depressed and stops in diastole.

Absorption—Sulphonamides when given by mouth are rapidly absorbed within 1 to 3 hours. Absorption is quicker when given in solution and alkaline medium. The peak in blood is reached in 3 hours, thereafter it gradually falls to zero in the next 24 hours. If the dose is repeated every 4-6 hours, a definite blood concentration can be obtained and maintained. All the sulphonamides with the exception of sulphaguanidine, succinyl sulphathiazole and phthalyl sulphathiazole are rapidly absorbed from the small as well as large intestines before the ileocaecal valve is reached. Sulphapyridine is absorbed somewhat slowly than other compounds. 30 to 60 per cent of sulphaguanidine administered is usually absorbed while the rest is excreted in the faeces in high concentration. Only little or none of the succinyl sulphathiazole is absorbed from the gut, only 5 per cent being recovered in the urine.

Distribution—After absorption the sulphonamides are generally distributed equally throughout the body with slight variations with various compounds. They tend to penetrate the C. S. fluid and peritoneal and other effusions. The distribution between plasma and corpuscles varies in degree with different compounds. This may be due to part of the sulphonamide being 'bound' to the plasma proteins. Sulphanilamide is said to be thus bound only 20 per cent, whereas sulphathiazole is bound about 75 per cent.

Excretion—Sulphonamides are excreted by the kidneys both in free and conjugated forms chiefly by glomerular filtration. The rate of elimination depends on the urine flow and not on the plasma level and that is why it is possible to wash out the drug by promoting diuresis. Diuresis thus favours excretion of the drug while a state of renal impairment will have the opposite effect.

Many of the acetyl derivatives are less soluble than the original compounds and consequently during excretion through kidneys they tend to crystallise and block the urinary passages. The extent of this acetylation varies with different compounds. Sulphanilamide and sulphapyridine are more readily acetylated than sulphathiazole.

Sulphonamides are also excreted in saliva, sweat and milk, in concentrations similar to those occurring in blood. They pass through the placenta into the foetal circulation also. The amount occurring in the milk is too small to exert any toxic or therapeutic action on a suckling infant, and sulphonamides need not usually be withheld from pregnant and lactating mothers on account of the child. Nevertheless it is probably wise to be cautious on such occasions.

Mode of action—The sulphonamides act upon susceptible micro-organisms by their bacteriostatic rather than bactericidal action. Phagocytic activity

is an essential part of the sterilising effect of sulphonamide therapy in infections. Probably the drug primarily acts upon the bacteria which are so altered as to be easily ingested by phagocytes, although they do not in any way stimulate the mobilisation of macrophages. Sulphonamides do not neutralise bacterial toxins to any great extent, though there is some evidence that they may inactivate certain endotoxins.

It is known that para-amino-benzoic acid is essential for the growth of bacteria. The sulphonamides are sufficiently similar in chemical composition to p-aminobenzoic acid to be used instead by the bacterial organisms if present in greater concentration. They do not serve the metabolic functions of the organisms so well and the result is interference with bacterial multiplication. The action of sulphonamides can be reduced or neutralised by small concentration of p-amino-benzoic acid or less effectively by certain other compounds like methionine or peptone, procaine, planocain, benzocain (compounds containing p-amino-benzoic acid group). If these anaesthetics are used at the same time action of sulphonamides will be weakened. While anaesthetics like cocaine, nupercaine, tropacocaine, etc. (which do not contain this group) can be used.

It is also suggested that sulphonamides are converted in the body into a substance which combines with the proteins available for bacterial nutrition, rendering it unfit for assimilation. Thus the bacterial metabolism is depressed and they are destroyed by the macrophages.

It is also known that sulphonamides undergo ionic dissociation in solution and the activity depends upon the number of anions available and not on the whole molecule. In alkaline medium more ions are available and thus they are able to produce better action.

With insufficient doses of sulphonamides, the bacteria become resistant to them *in vitro*. This has been noticed in case of pneumococci, gonococci, streptococci, etc. but fortunately in clinical practice frequency of this has not been established, but, however, the possibility must be kept in mind.

Routes of administration—(1) Oral: Sulphonamides are usually given by mouth. In order to facilitate their absorption tablets may be crushed and taken in alkaline medium (sodium bicarbonate or sodium citrate, 15-30 grains to each fluid ounce). This is the method of choice because of its simplicity and practicability.

(2) Parenteral route:

(*a*) Subcutaneous injection: This is useful in persistent nausea and vomiting. But it has no special advantage over other methods.

(*b*) Intramuscular administration is used as a substitute for intravenous route when good veins are not available or for some reason the I.V. route is not desirable. This method carries with it some risk. The sodium salts of sulphapyridine, sulphathiazole, sulphadiazine, etc., due to their high alkalinity may set up irritation and necrosis in the tissues. They can, however, be given intravenously and if given very slowly and no material escapes into the tissues, no deleterious effects are produced. But when it is absolutely necessary to give the drug intramuscularly, the number of injections should be as few as possible and the distance between sites of each injection should be not less than 3 inches. The injection should be given deep into the muscles and as far as possible from the important nerves.

(*c*) Intravenous administration: This should not be applied in routine treatment as absorption is fairly rapid by the oral route and subcutaneous route. It should be used when it is desired to attain a high concentration in blood rapidly, usually at the beginning of the treatment of a severe infection, or when for certain reasons oral administration is not possible.

Solutions to be used—Sodium salts are preferred for intravenous or intramuscular injection. The sodium salts of sulphathiazole and sulphapyridine are given in 10 per cent solution and of sulphadiazine in 5 per cent solutions. Sodium salts of sulphapyridine and sulphathiazole are supplied in powder forms in ampoules containing 1 g. each. Both for intravenous or intramuscular injection, the contents of one ampoule are dissolved in 10 c.c of sterile distilled water before use. Similarly sodium sulphadiazine is supplied in bottles of 0·5 g. each and a 5 per cent solution can be freshly prepared.

Dosage

Table 1 is for general guidance and in particular instances the doses may have to be modified to suit the individual patients or the special properties of the preparation given; for example, somewhat smaller doses are required for sulphamerazine or when there is a wide departure from the average weight of the patient, the corresponding allowance should be made in the dosage.

The duration of course is normally 6-7 days and it should be rarely prolonged beyond the 7th day.

Prophylactic doses of sulphonamides are often required, for example, in children undergoing tonsillectomy or women in labour. The dosage will vary according to whether the condition is severe or mild. In severe illness 9 g. daily for 2-3 days, then 6 g. daily for another 2-3 days and finally 3 g. daily for 2-3 days, then 4 g. daily for next 2-3 days

TABLE 1—GENERAL SCHEME OF DOSAGE

	Severe Infections (endangering life)				Mild or Moderate Infections			
	Adults	Children			Adults	Children		
		0-3	4-10	11-15		0-3	4-10	11-15
Initial dose ...	2-4 g. I.V. 1·5 g. by mouth	0·5 g. I.V. 0·5 g. orally	1 g. I.V. 0·75 g. orally	1·2 g. I.V. 1 g. orally	2 g.	0·5 g.	0·75 g.	1 g.
1st period of 2-3 days	Followed by 1·5 g. 4 hourly	0·5 g. 4 hourly	0·75 g. 6 hourly	1 g. 4 hourly	1 g. 4 hourly	0·5 g. 4 hourly	0·5 g. 4 hourly	0·75 g. 4 hourly
Second period of 2 days	1 g. 4 hourly for 2 days approx. ½ of the 1st period	0·5 g. 6 hourly	0·75 g. 6 hourly	1 g. 6 hourly	1 g. 6 hourly	0·5 g. 4 hourly for 3-4 days	0·5 g. 6 hourly	0·75 g. 6 hourly
Third period of 2-3 days	1 g. 6 hourly approx. ¼ of the 1st period	0·25 g. 6 hourly	0·5 g. 6 hourly	0·5 g. 6 hourly	1 g. 8 hourly	0·25 g. 6 hourly	0·25 g. 6 hourly	0·5 g. 6 hourly

and finally 2 g. daily for another 2 days. Total 24-32 g.

For children over 6 years half the adult dose is given and for children under three years one third of the adult dose is given.

Toxic and Side-effects of Sulphonamides

General—The patient may complain of malaise and discomfort. There may be a combination of nausea, headache, tinnitus, giddiness and mental depression. These are more frequent with sulphanilamide and sulphapyridine and less with sulphadiazine. Use of mild sedatives is sometimes helpful.

Gastro-intestinal—Vomiting is the commonest and most troublesome and frequently occurs with sulphapyridine. Vomiting is due partly to irritation of the gastric mucosa and partly to some central action. It can be reduced by giving crushed tablets in milk or fruit juice and keeping the patient on light diet. Alkalies or acids given simultaneously with the drug may be helpful. Before each dose, Tr. opii 5 minims or nicotinic acid with each dose may be helpful. Glucose drinks are also helpful. Vomiting is not an absolute indication for stopping the drug, but it can be given parentrally.

Diarrhoea sometimes occurs after administration of these drugs, but is never a serious problem.

Cyanosis—Appears early in the course of treatment and is due to formation of methaemoglobin. It is a reversible process and disappears soon after the drug is stopped. Although alarming to the patient cyanosis is not of much significance, and not an indication for stopping the drug. Cyanosis can be controlled by oral or intravenous administration of methylene blue which accelerates the conversion of methaemoglobin into haemoglobin. Cyanosis disappears in 24 hours with this treatment but may reappear later on. It is common with sulphapyridine and sulphanilamide and less with sulphathiazole and sulphadiazine or nil with sulphaguanidine and succinyl sulphathiazole.

Acidosis or ketosis—This is indicated by hyperpnoea and acid urine, or in case of ketosis by the smell of acetone in breath, drowsiness, vomiting and acetone in urine. In such cases large doses of sodium bicarbonate should be given and in cases of ketosis, glucose or sugar is recommended. Acidosis generally occurs after sulphanilamide, sulphapyridine, sulphadiazine and sulphathiazole, etc.

Drug fever—Occurs during administration or within 24 hours after termination of the course. It is more frequent with sulphanilamide, sulphathiazole and sulphamezathine. The fever may be accompanied by chills, headache, vomiting, tachycardia, skin eruptions, cyanosis, collapse. Stoppage of the drug brings down the fever but if it does not, agranulocytosis should be suspected.

Skin rashes—These generally appear about the 8th to the 12th day of therapy. The commonest rash is a discrete maculopapular eruption distributed over the face, neck, wrists and forearms. Urticarial and purpuric rashes have also been reported. Sometimes rashes may resemble German measles or even a scarlatinform rash may be met with. Sulphathiazole sometimes causes a condition very much like erythema nodosum. Even ex-

foliated dermatitis has been produced. The rash on fading may leave staining and desquamation.

The treatment is to stop the drug and give large amounts of fluids. The rash often disappears in 24 hours. Rash may be a prelude to some severe complication, so a total leucocyte count should be done immediately and other precautions taken.

Blood changes: (a) *Leucopenia and agranulocytosis*—Depression of both white and red blood cells may occur but the former is more common, ranging from a mild leucopenia to agranulocytosis. Mild degree of leucopenia is not important unless it rapidly progresses to below 4,000 cells per c.mm. Agranulocytosis is a very serious condition and is assumed to be present when the total leucocytic count is below 2,500 per c.mm. and total neutrophils below 1,000 per c.mm. Sulphanilamide and sulphapyridine both cause agranulocytosis but is more common with the latter. Sulphathiazole and sulphadiazine produce it less commonly whereas sulphamerazine and sulphamezathine have not been reported to cause this. It is caused more by a high total dosage of the drug rather than high concentration in blood at any time and that is why the drug should not be continued too long.

The clinical picture of agranulocytosis is often indefinite and difficult to diagnose without a blood count. The characteristic features are a rising temperature, drowsiness, loss of sleep, sore throat, cough, vomiting and aching pains in the limbs. This may be followed by severe septicaemia and ulceration of the throat and mouth. The treatment of this condition should be swift and drastic. The drug should be stopped immediately and large quantities of fluids started. In severe cases repeated blood transfusions should be given. Para-aminobenzoic acid in doses of 0·3 g. every 4 hours along with nucleotides gives a good leucocytic response. The dose should not exceed 10-20 c.c. intramuscularly twice a day for 4-5 days. Another leucocytic stimulant is pyridoxine (vitamin B_6). 100-200 mg. may be given intravenously every day for 5-6 days when symptoms usually subside in 48 hours. Folic acid has also been recommended. Glutathione and adenine sulphate have also been tried. For the secondary infection associated with it, antibiotic therapy should be applied.

Anaemia—A slow fall in red cells and a drop of 10-20 per cent in haemoglobin is fairly common after sulphonamide therapy. This disappears on stopping the drug and is not necessarily a contraindication. However acute haemolytic anaemia is a rare but dangerous complication and develops early in the course. It occurs more frequently in children with sulphanilamide. It is due to idiosyncrasy rather than overdosage and is usually preceded by nausea and headache. Then follow fever, jaundice, pallor and shock. The liver and spleen enlarge and plasma bilirubin is raised. Urobilinogen is present in urine. The drug should be stopped immediately and blood transfusion given. Inspite of active treatment mortality is high and relapses are common.

Effects on kidney and liver—There may be oliguria, anuria or even haematuria due to blockage of urinary passages by the crystalline deposits of less soluble compounds like sulphapyridine, sulphathiazole and sulphadiazine. It is liable to occur when the fluid intake is small or fluid loss is large and may occur within 10 days of therapy. There is pain in the region of loins or vague abdominal pain and a diminished output of urine which may develop into anuria.

The development of the kidney complications can be prevented by the administration of large quantities of fluids to maintain a minimum urinary output of 1,500 c.c. in 24 hours and the urine should be kept alkaline.

However, if the condition develops, the drug should be stopped. Heat should be applied to loins which generally gives relief. But if anuria or oliguria (less than 500 c.c.) continues for 23 hours, a cystoscopy should be done and a catheter passed without delay. Renal pelvis should be washed with 2·5 per cent warm sodium bicarbonate solution. The catheter should be left in position till normal urinary function reappears.

Sulphonamides also produce toxic effects on the liver in the form of hepatitis. It is more common with sulphapyridine and sulphathiazole but not after sulphadiazine. It occurs generally in the third week of administration. Symptoms are jaundice, enlarged liver and spleen and ascites. The condition may pass off or may become fatal. Previous cirrhosis is a contraindication. Hepatitis should be diagnosed from jaundice and haemolytic anaemia which occur in the first week. The drug should be stopped and plenty of fluids and glucose drinks started. Diet should be of high protein and carbohydrate with no fat (skimmed milk, boiled fish and eggs, etc.). Sulphanilamide and sulphapyridine are more toxic to liver while sulphadiazine is the least toxic.

Arthritis—Sudden onset of pain may occur in larger joints especially after sulphathiazole, and the skin over the joint may be inflamed. One or more joints may be affected. On stopping the drug, pain disappears.

Effects on nervous system—There are very rare complications. Symptoms may be delusion, hallucination, loss of memory, encephalitis and even psychosis. Peripheral neuritis is a rare manifes-

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tation and may be after sulphathiazole in large doses and for prolonged periods. The compounds likely to cause this are sulphanilyl sulphanilamides, sulphanilyl dimethyl sulphanilamide and methyl sulphathiazole and these should not be used.

Sulphonamides in Infections

Streptococcal infections—Sulphonamides are very effective against β-haemolytic streptococci —group A of Lancefield and group C. Groups B, F, G, H and K are unsusceptible but are also non-pathogenic. Similarly non-haemolytic and anaerobic streptococci are entirely unsusceptible to sulphonamides.

Sulphanilamide has reduced the mortality rate in streptococcal septicaemia to a very great extent. The best drug is perhaps sulphathiazole and high levels have to be maintained for about a week.

In streptococcal meningitis, sulphadiazine is the drug of choice and intensive doses should be continued till the temperature comes down and spinal fluid becomes sterile.

Sulphamezathine is preferred in cases of erysipelas due to its low toxicity and sulphathiazole when complications like septicaemia or pyaemia are present. In cases of tonsillitis and streptococcal sore throat and prophylaxis against development of rheumatic fever, sulphadiazine is quite effective. Prophylactic doses of sulphanilamide also reduce the incidence of sore throat and rheumatic relapses. The value of these compounds is doubtful in scarlet fever, unless treatment is started very early.

Otitis media due to streptococci should be treated from the beginning as a severe infection and adequate doses of sulphathiazole or sulphadiazine should be given. Resistant cases should be treated with penicillin. But at the same time local treatment and surgical attention are essential.

Streptococcal pneumonia is not so amenable to sulphonamide as pneumococcal pneumonia, although the mortality rate has been reduced. The incidence of empyema is not appreciably checked.

In osteomyelitis of streptococcal origin, sulphonamides have proved to be very effective both in acute and chronic cases. In acute cases large doses of sulphathiazole have to be given till the temperature remains normal for 2-3 days. Infection may reappear, if the drug is stopped too early.

In puerperal fever the mortality rate has been reduced by sulphonamide from over 25 per cent to less than 5 per cent. Compounds like sulphanilamide and sulphathiazole are all effective, but sulphadiazine is the drug of choice in such cases.

Sulphonamides have also been tried in cases of subacute bacterial endocarditis, but the results have not been very encouraging.

Staphylococcal infections—Staphylococci are not very sensitive to sulphonamides and in general penicillin should get preference. In severe staphylococcal infections like acute osteomylitis, severe carbuncle, septicaemia etc., in the absence of penicillin sulphonamide should be given in high dosage in such conditions and then the choice lies upon sulphathiazole which is the most potent of these compounds.

Pneumococcal infections—Pneumococci are also quite sensitive to sulphonamides but a little less than the haemolytic streptococci. Sulphadiazine and its derivatives, sulphathiazole and sulphapyridine are most effective, but the latter compound should not be preferred due to its toxicity. Moderate concentrations of these drugs usually yield satisfactory results, and should be maintained till the temperature has remained normal for 24 hours; thereafter the dose may be reduced to half for another 3 days.

Before the advent of sulphonamides, pneumococcal meningitis was invariably fatal. With sulphonamides the mortality rate has been reduced considerably; with penicillin the results are even better. Sulphadiazine is preferred in such cases due to its easy diffusibility into the spinal fluid. Sufficiently high doses have to be given and an initial dose of 5 g. intravenously followed by 1 g. 4-hourly should be given. This should be continued for at least 7 days after the clinical improvement has occurred.

Meningococcal infection—Meningococci are even more susceptible to sulphonamides than haemolytic streptococci. All the compounds are effective but sulphadiazine is the drug of choice and an initial dose of 5 g. intravenously should be given in severe infections. In meningococcal meningitis, sulphonamide therapy should be instituted as soon as the clinical diagnosis is made. Penicillin is effective, but as the response to sulphonamide is extremely good it is generally not indicated. The mortality rate has been reduced from 50-70 per cent to 1-9 per cent. The prophylactic doses of sulphonamides 2-3 g. daily for 3 days have reduced the incidence of cerebrospinal fever and carrier rate in epidemics of meningitis.

Gonococcal infections—Gonococcus is very sensitive to sulphonamides. Sulphanilamide, sulphapyridine, sulphadiazine and sulphathiazole are all effective, the latter being in concentration of 2 mg. per 100 c.c. Sulphathiazole and sulphadiazine are drugs of choice and the suggested dosage is 5-6 g. daily for 5 days in adults. Excellent results have been obtained by the use of

sulphonamides in the prophylaxis of gonorrhoea. Gonococcal valvovaginitis in children reacts very well to sulphathiazole.

E. coli infections—In such infections of the urinary tract almost all the compounds are effective. Sulphathiazole, sulphadiazine or sulphamezathine may be given in moderate doses till the urine becomes free from pus after which the dose may be reduced and continued for at least 7 days more. Alkalies should be given simultaneously to minimise the risk of precipitation of the drug in the renal tubules.

Dysenteric infections—In acute bacillary dysentery in adults, sulphaguanidine in doses of 3 g. three or four times a day for 3 days followed by 1 g. twice daily for 4 days has given satisfactory results. In severe infections the dosage may be increased to 5 g. For chronic cases a course of 5 g. 8-hourly for 5 days followed by 2½ g. 8-hourly for another 5 days may be given.

Recently other compounds like sulphadiazine, sulphamezathine or even sulphapyridine have been used with success in such infections.

Succinyl sulphathiazole and pthalyl-sulphathiazole are both slightly absorbed from the gut and are used in the average doses of 20 g. and 12 g. respectively daily in divided doses at 3 hour intervals. Pthalyl-sulphathiazole was inferior to sulphanylbenzamide, but both are superior to sulphaguanidine, in all respects especially against 'Sonne,' 'Schmitz,' 'Boyol' and 'Newcastle' strains.

Shiga infections are generally severe and in such cases it is advisable to give maximum dosage of 5 g. 3 or 4 times a day. These cases usually respond well.

Flexner dysentery infections respond well to moderate doses of sulphonamides. Sonne infections are clinically very mild and in this the aim of therapy should be to cure the convalescent carriers. Sulphaguanidine is not very effective that way. Sulphasuccidine and phthalyl-sulphathiazole have been reported to be effective but not entirely satisfactory.

Cholera—Sulphaguanidine was first used in the treatment of cholera in 1941 with favourable results. The dosage should be that recommended for acute bacillary dysentery. Sulphadiazine, succinyl-sulphathiazole and pthalyl-sulphathiazole have also been tried in this condition. But it is of utmost importance to bear in mind that sulphonamides used in cholera are likely to cause serious urinary complications unless an adequate urinary output has been established before commencing chemotherapy.

Plague—Sulphapyridine was the first drug employed in cases of plague with good results. Later on sulphathiazole was found to be more potent than sulphapyridine in the treatment of this disease. Sulphathiazole or sulphadiazine should be employed in the same dosage as in all other severe infections. Better results are obtained by combining this therapy with streptomycin.

Chancroid (soft sore)—For the treatment of this condition sulphathiazole, sulphadiazine, sulphapyridine or any one of their derivatives may be given in doses of 4 g. daily up to a total of 30 g. or till healing occurs. The administration of 2 g. of sulphathiazole before exposure to risk and twice afterwards was found to reduce the incidence of chancroid from 5·2 to 0·6 per cent.

Brucella infections—These organisms are sensitive to sulphonamides *in vitro* but results in human brucellosis have been uncertain. Initially the results were good but then relapses occurred. Treatment is most effective in acute cases of less duration. Sulphadiazine is the drug of choice. An initial dose of 4 g. is followed by 1 g. four-hourly for 10-12 days.

Caution and Contra-indications

In the treatment of acute infections a large initial or a loading dose has to be given in order to get an effective level of the drug in blood quickly. In more severe cases this can be achieved by administering the loading dose intravenously. This is because the sulphonamides act better on a smaller number of bacteria by checking their multiplication.

If large doses are administered, frequent leucocytic counts for any indication of agranulocytosis should be performed. Sufficiently large quantities of fluids (not less than 5 pints or 3,000 c.c.) have to be given to ensure a large quantity of urine output so as to minimise the chance of urinary blockage.

The concentration of the drug in blood must be maintained at an effective level throughout 24 hours. To ensure this, the drug has to be repeated every 4-6 hours. The administration of the drug should not be stopped too soon as there is risk of recurrence and drug resistance. If, however, the drug has to be continued for more than 7 days or more than 300 g. have already been given, a leucocytic count is indicated.

It is said that the action of sulphonamides is reduced by the presence of peptones, as for example, that produced in an undrained pocket of pus or in necrotic tissue in a wound. This can be overcome by draining away the pus.

Phagocytosis is an important factor in sulphonamide therapy and sometimes the natural defences of the body may be poor and may not be able to deal with the organisms in spite of bacteriostasis having been produced by the drug.

In urinary infections, comparatively smaller doses of sulphonamides are required as the concentration of the drug is much higher in urine than in blood or tissues.

Pregnancy is not a contra-indication to the use of sulphonamides though they pass through the placental barrier. But this prolonged use is not recommended.

Where toxic reactions have followed their previous use, sulphonamides are contra-indicated. In cirrhosis of liver, they should be used with caution. In anaemia, granulopenia and jaundice they are either contra-indicated or used with the greatest possible caution.

Sulphonamides are very potent compounds and the difference between their therapeutic and toxic doses is very small. Therefore, their use should be under strict guidance of physicians.

Combination of Sulpha Drugs

Recently it has been pointed out that a combination of two or more compounds has a better effect on severe infections, because it permits usually smaller doses of each compound than either drug alone showing the phenomenon of synergism. Thus a combination of equal parts of sulphathiazole, sulphadiazine and sulphamerazine is said to reduce or eliminate renal obstruction due to crystaluria without administration of alkalies. Allergic reactions like rashes, fever, etc., are also less. On this principle, recently preparations have come into use which are less toxic and more effective.

The practitioner should however, realise that there is always certain risk attached to adequate sulphonamide therapy. Formerly sulphonamides were the only effective remedies for bacterial infections. But with the coming in use of even more effective and non-toxic antibiotic, penicillin, the use of sulphonamides in such infections has narrowed down considerably. Sulphonamides should be given in infections less sensitive to penicillin or non-susceptible to penicillin. But the development of newer antibiotics like streptomycin etc. have filled up the gap left by penicillin and so the use of sulphonamides is becoming further narrowed down. However, in the oral treatment of several common infective conditions, this group of drugs will continue to occupy a respected place in the armamentarium of the modern practitioners for many more years to come.

SPECIAL ARTICLE

PHARMACEUTICAL INDUSTRY IN INDIA —PLANNING FOR THE FUTURE

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It was during the First World War and the years following, that the corner-stone of the present drug industry was laid in this country. By this time, the difficulties that faced the manufacturers had to some extent been surmounted, the situation had become much more favourable, and optimism prevailed amongst those interested in the industry.

Besides the preparation of extracts, tinctures and a few patent fever cures and allied products which had hitherto engaged their attention, some of the concerns now attempted manufacturing the more complicated and scientific preparations. It was during this period that the venture was made by an Indian firm to introduce in the market vaccines and antitoxins of Indian make. It was indeed a bold attempt because it took up a challenge and broke the age-long belief that Indian manufacturers were not competent enough to undertake the preparation of such specialised medicinals. The challenge was won, these India-made biologicals when tested by international authorities received the seal of approval. Emboldened and heartened, the industry tried to expand its activities and started preparing many of the drugs, pharmaceuticals and surgical dressings that were so far being exclusively imported from abroad, and we felt that soon we would have a mature and well established drug industry in India.

A turning point however came during the years of the Second World War. The industry had another upheaval, and a large number of manufacturing units received licences for preparing drugs and pharmaceuticals. In and around the city of Calcutta alone about a hundred such new enterprises started operations. Due to the restrictions in imports and increases in internal demands these new ventures, most of which were owned by individuals or small groups, were a success. They however mostly confined their business to the rural and underdeveloped areas and tried to replace the products of the established houses on merits of cheapness.

As their aim was 'cheapness', the inevitable consequences followed. These cheap preparations were mere apologies for medicaments ; there was no guarantee for their quality or purity. Most of

these small units are still operating and I believe some more have since been added to their list.

Even such important items as parenteral preparations of alkaloids, grape sugar, normal salt solutions, liver extracts, vaccines and vitamins for injections are being prepared in many of these units. As their funds are limited, they have very little of appliances and equipment and have on their staff people who because of the low wages offered could not be considered to have the technical skill necessary for such important operations. Although these preparations strictly do not come under the category of spurious drugs, they are none the less dangerous and could cause the same harm and mischief as the fake products. If the State and the public are agitated over the menace of spurious drugs, they should also have the same feelings towards these improperly prepared and unstandardised products and launch a campaign to stop their manufacture. Apart from this, these mushroom firms have done incalculable harm to the fair name of the Indian pharmaceutical industry and are responsible largely for the scepticism that has again crept into the people's mind and the apathy that has developed as a consequence for Indian made pharmaceuticals in general. An analysis of the present drug trade will reveal a general tendency of patronage for imported preparations. Since the last war, the number of foreign manufacturers importing medicinals to India has considerably increased. Although restrictions on foreign exchange do not permit a free trade, it is evident that even some countries whose pharmaceutical products were unknown in this country have found sufficient encouragement for trade with India. The Indian pharmaceutical industry should be on the alert, otherwise there are sufficient indications that a near catastrophe lies ahead of the industry. To avert this crisis, the industry has to organise itself, it has to see that the undesirable mushroom companies withdraw from the field, and finally it has to change its outlook and plan for its future.

Tracing the history of the growth of the pharmaceutical industry in the United States of America, it will be evident that the corner-stone of its present structure was laid after

(1) the promulgation of the Federal Food and Drugs Regulations in 1906 ; and
(2) the formation of the American Drug Manufacturers' Association in 1912.

The enforcement of regulations in the methods of manufacture and sales and the laying down of certain ethics for the membership of the association gave a healthy tone to the industry, and brought a scientific outlook in the trade.

In this country, the Indian Drugs Act (1940) and the Drugs Rules (1945) were formulated to straighten out the defects in the industry and trade. The Central Drugs Laboratory of the Government of India and the different State Drug Control Laboratories are functioning to check the qualities of drugs and pharmaceuticals that are being manufactured in or being imported into this country. But unfortunately most of the undesirable products manufactured by the undesirable producers move through channels where State vigil fails. It is necessary that an all-round effort be made to tackle the menace of these types of medical preparations.

The cities of Bombay and Calcutta are the principal drug manufacturing centres in India. Through these two ports most of the foreign drugs are imported and both these cities are the biggest wholesale and retail drug markets for the country. The municipalities of both these cities could set up a rigid drug control system patterned after the Food and Drug Control Sections of the New York City Board of Health. Such departments could not only control the manufacturing establishments and their methods of processings, but also check the samples that are released for the wholesale and retail markets. Lately the Calcutta Municipal Corporation has launched a campaign against adulterated foods and spurious drugs. While commending them for this initiation, may I suggest they also consider the menace of the unstandardised or the improperly prepared drugs that are being manufactured within the limits of the city.

A word for the 'cosmetics' is also necessary. In the United States, the Federal Law demands that the quality of cosmetics are also scrutinised in the same way as that of the foods and drugs. The harm that comes from badly prepared cosmetics was revealed to me at the Food and Drugs Administration Headquarters in Washington, D.C. It is a tragedy that this section of trade has no supervision or control in this country. If the municipal regulations for food and drugs are amended to bring cosmetics into the list, it will be possible to eliminate many of the harmful products that are being sold at the counters today.

The American Medical Association's headquarters at Chicago has a Council of Pharmacy and Chemistry and maintains a well equipped laboratory, and a library with competent technical staff. The Council scrutinises new pharmaceutical products, foods for babies and invalids, surgical appliances and instruments, etc. The journal of the Association in its columns reports on the quality or suitability of these preparations, and grants to the deserving the Seal of Approval of the Council. The manufacturers send samples to the

Council, the seal helps them to promote sales. The medical profession also gets information about the latest preparations through the columns of the journal. It is a service to the profession as well as to the trade. The Indian Medical Association, which is the largest representative medical organisation in the country can emulate this scheme and thus help the genuine promoters in the industry. If the better class manufacturers come forward with funds to help the Association, there should be no difficulties to set up such an organisation. The larger organisations who are seriously interested in promoting the interests of the industry should form an All-India Pharmaceutical Manufacturers' Association (I believe there is already some form of an organisation), which by enforcing rigid regulations for membership, and setting up a code of ethics could eliminate many of the undesirables from the trade. This organisation can even set up a central control laboratory where all members could send their preparations for final analysis and tests. This laboratory can also plan research sections for conducting research in pharmaceuticals, which as I will point out later on, is urgently necessary for the welfare of the industry.

The Indian pharmaceutical industry, I feel, so long has been treading along the path of least resistance. The bulk of the trade has been more or less patterned on the same lines, almost every manufacturing house has been interested in the same types of preparations and have mostly been dealing with proprietary preparations which are substitutes for similar imported products. This has not only created an unhealthy competition, but glaringly proves that the industry lacks in originality and the spirit of adventure. An analysis of the conditions of the trade reveals that the manufacturers are really not to be blamed for this unhappy state of affairs.

The manufacturers in this country have been compelled to follow this policy due to certain difficulties that confront them. As all the essential ingredients, the chemicals, reagents and solvents, have to be obtained from outside the country and as the basic chemical industry has not been developed, the industry is compelled to take up a secondary or subsidiary role. This difficulty has to be removed if a pharmaceutical industry is to be planned for future India. Unless the basic chemicals, reagents and solvents are manufactured in India, not only this industry, but also the research institutions of the country will perpetually have to face the problems of supply and will be left at the mercy of foreign trade conditions. The industrialists who are interested in the future of the trade, should plan the manufacture of basic or fine chemicals, reagents, solvents, etc., so that everything needed by the pharmaceutical industry would be available in the country. This would enable the drug industry not only to run more economically and lower the costs of production but also would help them change their outlook and encourage them to take up preparations which hitherto they have avoided on the issue of heavy costs of production. The heavy chemical industry has made fairly good progress in recent years. I hope they also would plan so that some of the essential items for the manufacture of pharmaceuticals, those that are at present being imported from outside, are made available here.

The future possibilities of this industry are immense. As medical aid becomes more available to the rural areas and the purchasing power of the people increases, there will be greater demand for drugs than today. With mass education, there will grow health consciousness, people will be more interested in problems of health, nutrition and in methods of preventing disease. They will naturally ask for such preparations as would help them live healthy lives. In the programme for the future development of the industry there should be no dearth of capital, and all future plans should take into consideration the drawbacks and defects that exist today ; so that it could take full advantages of the future market that would inevitably result from the greater demands. It should therefore have as its aim the manufacture of items that are in demand by the medical profession and the public, specially taking into consideration all such as are not prepared in the country today. Schemes for preparations of insulin and its modifications, essential vitamins and amino acids, steroids, synthetic and chemotherapeutic agents, e.g., antimalarials, sulpha-compounds, P.A.S., etc., plasma substitutes and above all antibiotics, the modern miracle drugs, should have priority in the future development programme of the trade. If the industry for basic reagents and fine chemicals develops, there should be no cause for pessimism for such ventures.

The thought naturally comes back again, whether these Indian preparations will meet the favour of the public and would the medical profession have faith in the Indian substitutes? The preference, or perhaps the craze, for foreign preparations does not come from an inferiority complex. The pharmaceutical industry in the United States and Europe by making valuable contributions in the field of therapeutics, has won the confidence of the medical profession and created a prestige for itself . It cannot be denied that many of the outstanding antibiotics have been discovered in the research laboratories of commercial firms. In the domain of synthetic chemistry, the

pharmaceutical insustry's share is in no way less than that of the academic institutions. The industry can also proudly claim the credits for improvements it has brought about in some of the important therapeutic agents, e.g., insulin, liver extracts, glandular preparations, antitoxins, etc.

The Indian pharmaceutical industry has to enhance its own prestige by starting schemes of research in therapeutics. It is a matter of shame, although nearly half a century old, there has not been any significant original contribution by the industry, that some of the outstanding cures for tropical maladies should have come from countries where these diseases do not exist. If the industry feels that talent is lacking in India for this type of work, they are mistaken. In the United States of America, an Indian, Dr. Subba Row was the head of the Research Divisions of a pre-eminent commercial laboratory, and was responsible for some of the outstanding products introduced by that company. During my recent travels in that country, in another pharmaceutical organisation, I met Dr. Naidu, who was described as a 'wizard' by the management of the company. An Indian, Dr. Bhattacharya shares the credit along with some other members of the staff of the Illinois University for discovering a very important antibiotic. In the United States and Great Britain, Indian scientists and technicians have occupied and are still occupying important positions in different productive industries. It has to be admitted that the Indian pharmaceutical industry has to a large extent failed to chain the Indian talents to promote the interests of the industry. It may be because the outlook was different, it may be because the conditions and prospects in service were not attractive.

Instead of mere calculations on bigger sales, bigger profits, or bigger dividends, a good portion of the capital and profits should be earmarked for research. Research in industry always pays in the long run.

During recent years several Indian-Foreign combines have started operations in India. I personally welcome these projects. It will be a tragedy if these fall in the same rut as those who are already in the field, or play the role of mere packers and bottlers for bulk supplies from foreign laboratories. These combines have a brilliant chance and a bright future. They could for instance initiate the manufacture of basic chemicals, reagents, solvents and build up a pharmaceutical industry complete in the fullest sense of the term. These combines instead of getting interested in preparations that are already being manufactured in the country could start producing only those items which hitherto have not been possible to prepare here. They could start research laboratories and train up young scientific talents in research in pharmaceutics. There is a vast field for exploration. Researches, planned on proper lines may yet reveal many a product of indigenous medicines as useful as *Rauwolfia serpentina*. Proper screening of samples of Indian soil may lead to the discovery of newer antibiotics. The problem of poliomyelitis, I believe is going to be a big headache for the future and its spread likely to increase with improvements of general sanitation of the cities and towns. In the United States, schemes are being worked out to utilise every human placenta for preparing gamma globulin—the only preventive available for this deadly malady and one commercial laboratory in the neighbourhood of New York has already arrangements for collecting all the placentas from the maternity hospitals of New York city for preparing this valuable therapeutic agent. These large combines have the funds for the equipment and staff necessary for all such projects. They could in the initial stages get a team of personnel to set up the organisations here and thus usher in a new era of the pharmaceutical industry in this country.

The question of nationalisation of the drugs and pharmaceutical industry naturally arises at this stage. The pharmaceutical trade in almost all the progressive countries of the world, except perhaps the U.S.S.R. is being run by private enterprise. In the United States, Great Britain, Switzerland and some of the European countries, the standards attained by the industry is a clear proof that it can take care of itself. By maintaining scientific standards in methods of preparation, by enforcing rigid systems of quality controls and above all by carrying out research in the fundamental problems of therapy, the industrial organisations in this country could well maintain their lofty ideals of service to humanity. A State managed industry under such conditions can in no way function better. Instead of taking over the manufacture, the State at this stage of national development, can give the industry the necessary directives, ideas on how to plan, what to prepare, and solve the problems that face the manufacturers today, at the same time maintaining strict surveillance over the quality of the products released for the use of the suffering public.

Now that the Pharmaceutical Enquiry Committee has submitted its report, the industry will have valuable suggestions which would help it to reorganise itself so that it could ultimately take up the responsibilities in the future development programmes of the nation.

CASE NOTES

PAPILLARY CYSTADENOMA LYMPHOMATOSUM (WARTHIN'S TUMOUR)

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X, H.M. 49, complained of a swelling in the anterior portion of the neck just below the angle of the mandible, on the right side. It started as a small swelling about the size of a pea about 8 years back and attained the present size of a hen's egg during the period. It was freely movable and smooth. Of late the patient used to feel some discomfort on movement.

The tumour mass was easily removed and was capsulated. It was cystic in consistency. On section some semisolid mucin-like substance came out.

Microscopically (Fig. 1, *vide* Plate), the tumour mass was composed of an epithelial parenchyma (B) and a lymphoid (D) interstitial tissue. Slender finger-like papillae with branches with club-shaped ends (A) could be seen projecting into the cystic cavities. The cavities contained an eosinophilic granular substance with occasional lymphocytes and desquamated epithelial cells (C). On higher magnification the papillary projections were seen covered by a layer of high columnar cells (E). A few goblet cells could be seen among them. The interstitial lymphoid tissue was seen aggregated between the cystic cavities in the form of germinal centres.

DISCUSSION

This neoplasm at the angle of the jaw is a very rare one. On searching the literature it is found that only a few cases have so far been recorded and none in Indian journals. The origin and nomenclature of this tumour is controversial. The causes of confusion were due to the fact that designation of any tumour in the cervical region with cystic and papilliferous pattern was termed as papilliferous cystadenoma lymphomatosum and indiscriminate use of the term adenolymphoma including Warthin's tumour, and other tumour growing in the parotid region with lymphatic and epithelial elements. Different names coined by different workers at various times added further difficulties.

Clinical feature of this tumour is well established. It is usually found in the males of advanced age. The ratio between affected males and females is 7 :1. It occurs in the parotid gland. Bilateral affection has been recorded. Malignant change has never been noticed.

Earliest record was made by Albrech Artzt although the exact origin of the neoplasm was not established by him. Warthin (1920) established the true nature of the tumour and put it on definite foundation. In his opinion it is a 'teratoid tumour' arising from the dystopia of the mucosa of the auditory tubes caused by developmental disturbances of the analage of this tube. Thompson and Bryant (1950) established the histogenesis of the tumour. They think that the origin is from the neoplastic proliferation of those ducts of parotid gland normally embedded in lymph nodes.

ACKNOWLEDGMENT

We take this opportunity of thanking Dr. M. Pan, Principal, and Dr. M. Sarkar, Superintendent, Calcutta National Medical Institute, for permission to publish the records and Sri J. Bose for technical assistance rendered.

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INTESTINAL LESIONS IN CONGENITAL SYPHILIS

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Syphilis rarely affects the small intestine. Karsner (1943) states that such lesions may be either congenital or acquired. The congenital lesions are usually in association with other visceral manifestations. The commonest lesion is a small flat single or multiple, gumma-like process which he considers is found most commonly in the ileum. These lesions may ulcerate. He refers to acute inflammation from secondary infections often obscuring the perivascular infiltration of lymphoid and plasma cells and the obliterative arteritis.

MacCallum (1942) refers to tertiary lesions of the small intestine usually localised to the jejunum or upper ileum which form flat elevations. Multiple ulcers can form rings around the gut and produce strictures. He considers that the only commonly found lesion in the intestine is present in the rectum. He mentions changes which can occur in the submucosa of the small intestine with infiltration by wandering cells and some formation of connective tissue, ulceration and abscess-like areas of necrosis occur.

Cappell (1951) states that in congenital syphilis multiple lesions are not infrequent especially in the ileum. He considers that they form patches of inflammation which ulcerate and can resemble tuberculous lesions or may appear as miliary gummata.

However a search of the literature suggests that syphilitic lesions in the small intestine have been seen rarely and spirochaetes have not been recovered from such lesion frequently. D'Aundy and Pearson (1939) state that intestinal lesions were found in 1·3 per cent of 230 cases of syphilis in infants, who came to autopsy in the Charity Hospital. They consider that intestinal syphilis is practically always associated with more severe visceral lesions. In 1939 they could not find any case recorded in the English or American literature in which spirochaetes had been identified. In 50 per cent of the reported cases of intestinal syphilis the process has been seen in stillborn or macerated foetuses. In 27 per cent of cases death has occurred within 24 hours but cases have been reported which have lived for as long as three years. Spirochaetes were, according to them, first identified in the intestine by Verse in 1906 and most of the literature quoted is German. They refer to the way coils of intestine may be involved in a plastic peritonitis. They consider that the upper parts of the ileum and lower and upper parts of the jejunum are the favourite sites of infection. In their three cases they demonstrated an abundance of spirochaetes. In one case there were communications between adjacent loops of small intestine. In the second case there were yellow plaque like elevations. In the third case there were numerous elevated circular thickenings of the jejunum and ileum. In all cases pancreatic fibrosis was present and this was considered to be the most reliable sign of congenital syphilis. They comment on the loss of the mucosa in the affected areas with well marked endarteritis and infiltration by inflammatory cells.

Stokes (1944) considers that the most complete account is that given by Nishikawa from Rudolf Virchow Hospital in Berlin in which he critically reviewed the literature and reported six authentic cases.

Tuttle (1932) has reported multiple strictures in the first part of the jejunum in a woman aged 38. In this case Warthin demonstrated numerous spirochaetes.

Case Report

A female baby at birth took only one breath and died. The autopsy was performed two hours after death. The baby weighed 1500 g. and had a very swollen abdomen. When the abdomen was opened adhesions were found between the loops of jejunum. This portion of jejunum contained a number of ulcers on the mucous membrane. These were mainly longitudinal and measured 1 × 1½ cm. The borders of the ulcers were haemorrhagic. There were a number of similar ulcers in the ileum but these did not have a haemorrhagic border. A few small ulcers were noticed in the ascending colon. There was no sign of perforation or communication between adjacent loops of bowel. The liver was enlarged, pale brown in colour and firm in consistency. The gallbladder contained white bile ; the biliary passages were not obstructed but no pigmented bile was present. The spleen was enlarged and on section appeared congested and fibrous. The pancreas appeared solid and fibrosed and showed little evidence macroscopically of a glandular pattern. The right lung floated in water but the left lung was completely atelectatic and sank. The kidneys, urinary tract, adrenals and genitals showed no significant lesions.

Histological Report :

Intestine—At the site of ulceration the mucosa has been completely destroyed and the submucosa is heavily infiltrated with cells which are mainly lymphocytes but a few scattered plasma cells are seen. The vessels show well marked endarteritis and the inflammatory cells can be seen to surround the vessels. There is some fibrosis. The histological picture is a little confused by the intermingling with this tissue of a number of neutrophil polymorphonuclear cells (Fig. 1 *vide* plate). Silver staining by a modified Krajian's method for spirochaetes shows very many spirochaetes crowding the field (Fig. 2 and 3 *vide* Plate).

The liver showed marked fibrosis with an increase of fibrous tissue in the portal tracts and between the liver cells. There was well marked foetal erythropoiesis. Both the spleen and pancreas showed marked fibrosis. Silver stains revealed numerous spirochaetes in the liver, spleen and pancreas.

The lung showed marked fibrous tissue proliferation around the bronchioles and in the interalveolar septa. There were scattered collections of lymphocytes.

The kidney and cervix showed no lesion.

Summary

This case is reported because of the unusual appearance of ulceration in the small bowel in a case of congenital syphilis. The diagnosis was confirmed by the finding of numerous spirochaetes in the intestinal lesion as also in the liver, spleen and pancreas, which showed the typical fibrosis of this condition. The intestine was so full of spirochaetes that pieces of it have been used as a control when we have been examining other tissues for spirochaetes.

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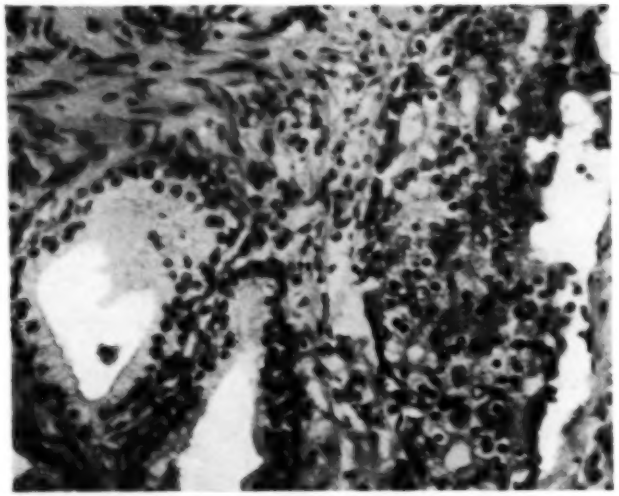

Fig. 1—Shows sheets of cancer cells lying adjacent to hypertrophied glandular acini. H. & E. × 180

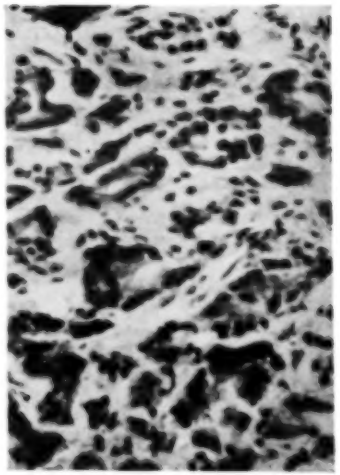

Fig. 2—Adenocarcinoma prostate. Shows irregularly proliferated acini separated by fibrous tissue. H. & E. × 60

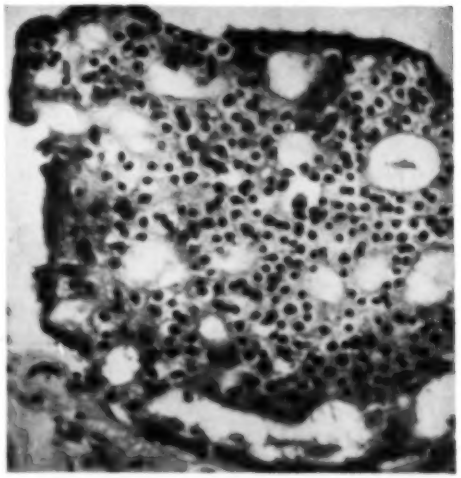

Fig. 3—Adenocarcinoma prostate. Shows intra-acinar proliferation of cells with a cribriform arrangement. H. & E. × 180

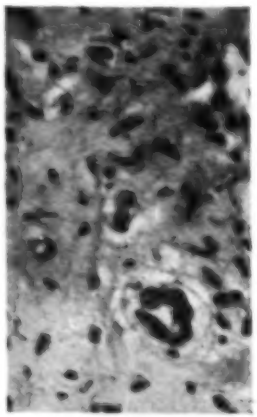

Fig. 4—Scirrhus carcinoma. Shows isolated groups of tumour cells separated by abundant fibrous stroma. H. & E. × 120

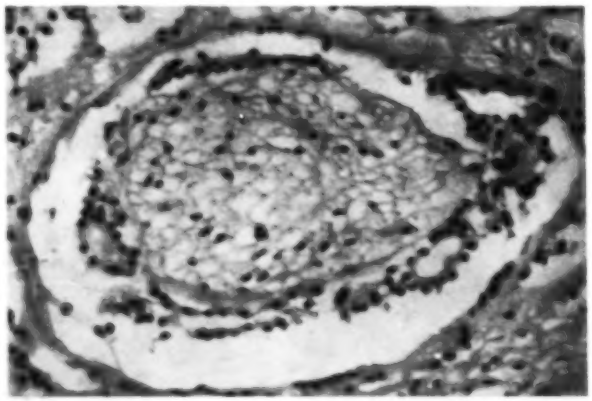

Fig. 5—Shows tumour emboli in perineural lymphatic. H. & E. × 80

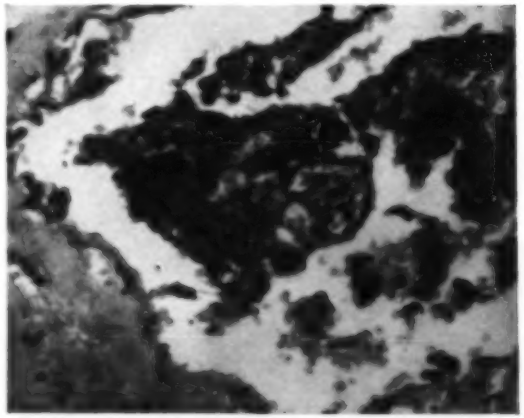

Fig. 6—Shows tumour embolus in a vein. H. & E. × 80

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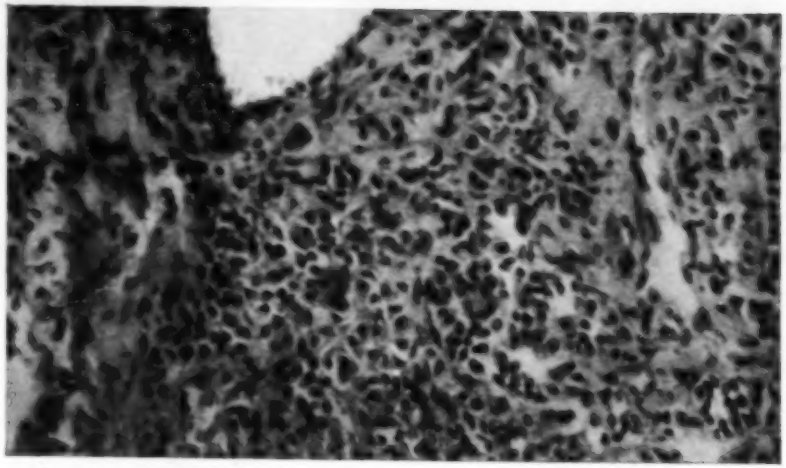

Fig. 7—Spheroidal cell carcinoma. Shows marked cellularity of the tumour. H. & E. × 80

MANGALIK ET AL—*Carcinoma Prostate—A Histopathological Study (pp. 1-4)*

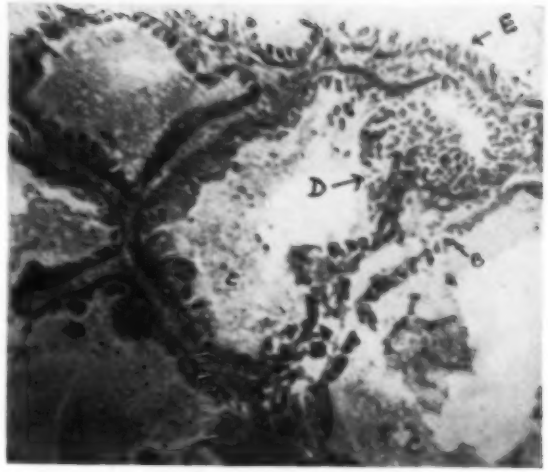

Fig. 1—Photomicrograph of the section

GUHA ET AL—*Papillary Cystadenoma Lymphomatosum (p. 23)*

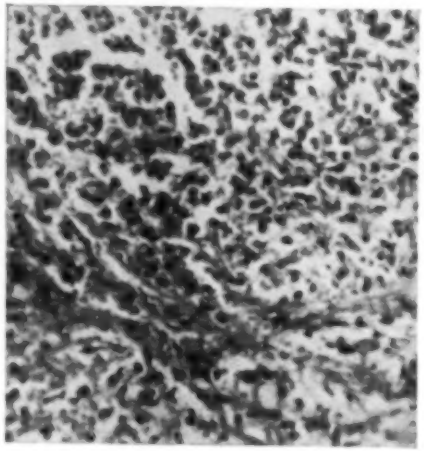

Fig. 1—Lesion in the intestine showing endarteritis and a mixture of acute and chronic inflammatory cells. H. & E. × 110

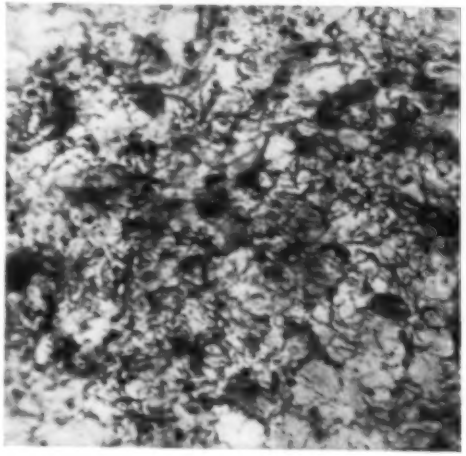

Fig. 2—Spirochaetes in wall of intestine—silver stain modified Krajian's method × 460

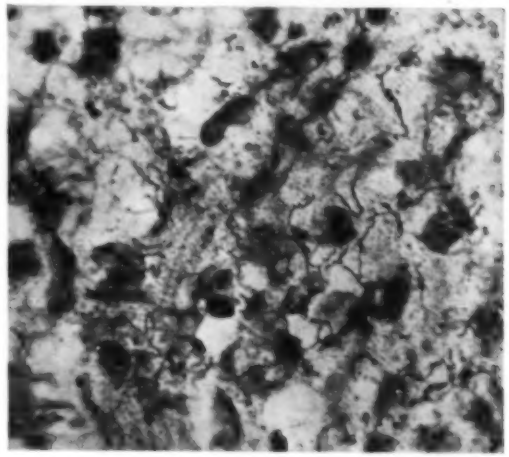

Fig. 3—Spirochaetes in wall of intestine—silver stain modified Krajian's method × 900

GAULT AND JAYARAJ—*Intestinal Lesions in Congenital Syphilis (pp. 23-24)*

JOURNAL OF THE
INDIAN MEDICAL ASSOCIATION

CALCUTTA, JUNE 1, 1955

PHARMACEUTICAL ENQUIRY COMMITTEE'S REPORT

Government are fond of commissions and enquiry committees. They keep many men busy and, presumably, keep the people contented. The bodies set up turn out workmanlike jobs but action is seldom taken on their findings. Government "study" the reports, whatever study may mean and the recommendations arrived at after much expenditure of labour and public money are more often than not thrown into the limbo of official oblivion. One of the classical instances of such is the Bhore Committee's monumental report. This is now no more than a reference book. We trust the Report of the Pharmaceutical Enquiry Committee 1954 will not suffer the same fate.

The Enquiry Committee headed by Major-General S. L. Bhatia was appointed by the Government of India in the Ministry of Commerce and Industry by a Resolution dated the 14th February, 1953.

It is a matter of deep regret to us that the Committee was deprived, due to sudden death, of the counsels of Dr. A. K. Sen, who had been for several terms the senior vice-president of the Indian Medical Association and whose knowledge of the pharmaceutical industry was as intimate as it was deep and extensive.

The Committee was set up to make a thorough enquiry into the working of the pharmaceutical industry as a preliminary to considering what steps Government should take to establish it on sound lines in the interest of the country's health and economy.

The terms of reference were quite comprehensive. They were:

(*i*) To study the working of the existing pharmaceutical concerns in India with particular reference to
- (*a*) the demand for the drugs produced and their essentiality;
- (*b*) the quality of the drugs;
- (*c*) the cost of production;
- (*d*) the efficiency of the process employed; and
- (*e*) whether the product is made from imported intermediates and penultimate products or from basic raw materials and chemicals;

(*ii*) To study the operation of foreign and/or Indian concerns, who import drugs and pack them in the country. The extent of the tie-up between the wholly or partly owned Indian concerns with foreign companies;

(*iii*) To recommend steps for encouraging the manufacture of important drugs, which are imported into the country;

(*iv*) To enquire into the scheme of distribution of pharmaceutical products, whether imported or manufactured or packed in the country, the profit margins to Trade or Industry and the part played in this by purely Indian as well as other concerns;

(*v*) All ancillary matters connected with the above.

The Committee did a thorough job and its Report, a sizeable tome of over 400 pages, contains nine chapters, the first being an introductory one. The other eight chapters contain the findings and recommendations of the Committee. They deal with

I. The pharmaceutical industry—its scope and development in India and elsewhere and its present position in India.
II. The industry's basic raw materials and packing materials.
III. Demand and production, essentiality of drugs, cost of production and efficiency of processes employed.
IV. Standardisation, quality control and administration.
V. Research work.
VI. Distribution and advertisement.
VII. Medical profession and the pharmaceutical industry.
VIII. Technical training for the profession of pharmacy.

The volume ends with a summary of the recommendations, conclusions and acknowledgments. There are also a number of valuable appendices and a bibliography.

The recommendations of the Committee are an organic whole and the Report sounds a warning that unless they are implemented *in toto*, the desired results may not be achieved. Partial implementation of the recommendations may even lead to difficulties.

The future of the industry says the concluding part of the Report, depends on the efforts made by the manufacturers to produce pharmaceuticals and drugs starting from *basic chemicals* (italics ours) within the country itself. To achieve this, considerable technical knowledge, special plant and equipment, laboratory control and facilities

for research are necessary. It will be the duty of the Government, therefore, says the Report to "(*a*) extend all possible help to manufacturing organisations to provide themselves with these facilities so that they may develop on a regulated and planned basis ; (*b*) co-ordinate the interests of manufacturers, traders and consumers ; (*c*) see that the highest ethical standards are maintained in this industry and trade."

We are in full agreement with these views as we are with the recommendations of the Committee generally.

The Committee has rightly emphasised the need of manufacturing pharmaceuticals starting from basic chemicals. Our manufacturers must not be mere packers ; nor must they content themselves with converting intermediate products. The necessity therefore arises of manufacturing fine chemicals and primary drugs. We feel in this connection that unless the basic chemical industries are developed, the economic production of fine chemicals, drugs, dye-stuffs, explosives, etc., is not possible. The chemical industry should be visualised as a chain of interlocked industries in which the by-product of one is the raw material of another. The entire industry tends to be uneconomic without this interlocking. The development of scientific coal carbonisation and the coaltar distillation industry is a need both national and urgent. If the private sector is unable to undertake such manufacture, Government should themselves undertake to produce them either by setting up new factories or by expanding existing Government factories.

The Committee suggests various improvements in the Government factories in the different States. Less duplication, better co-ordination, improved equipment, introduction of business methods and new products are some of the suggestions. The Committee further suggests that the dumping of foreign quinine into India should be prevented by the imposition of custom duties on foreign quinine and antimalarials. We can understand the curb on quinine imports but the ban on synthetic antimalarials as suggested by the Committee will, we believe, adversely affect the people, especially the poorer section, who needs antimalarials most. The best course is of course to produce synthetic antimalarials in the country by private firms or in Government factories. Pending such time as they are actually manufactured here, liberal imports should be allowed.

We are in agreemept with the view that the penicillin factory now under construction at Pimpri, should be expanded to produce other antibiotics and chemotherapeutic products like streptomycin, synthetic antimalarials, sulpha drugs and vitamins. But we feel that in view of the total needs of the country and the large number of items required, aid and encouragement should be extended to firms who would actually manufacture one or more of these items.

The Committee has rightly emphasised that the size of an economic unit as envisaged in foreign countries does not apply *in toto* for conditions existing in India. Even if the demand for an essential drug is not enough to justify economic production, production should nevertheless be undertaken and Government should give protection to the industry to withstand foreign competition until such time as the demand rises to an economic level.

Regarding the setting up of foreign firms in India the views of the Committee are that these should not be permitted unless they undertake the production of new drugs or drugs which are not produced in India. The Committee also lays down the guiding principles to be adopted before permitting collaboration with foreign firms. In cases where imports of finished products like synthetics, antibiotics, vitamins and hormones have to be maintained in view of their importance, imports should gradually be reduced and the existing processing capacity of the country should be utilised fully by importing them in bulk and processing them until their production develops in the country.

The Committee points out in this connection that patent laws hinder the development of the synthetic drug industry. Foreign firms who hold the patents are unwilling to relax their rights and demand heavy royalties from manufacturers using these patents. The Committee suggests the Government to consider if they can abrogate the International Patent Registrations to enable manufacturers in this country to make essential pharmaceuticals without having to pay heavy royalties. The Committee points out that a similar step was taken in Japan before the last World War. This step helped Japan's drug industry to come up to the level of other advanced countries. What has benefited Japan may prove beneficial to India also.

Substandard and spurious drugs are a serious and mounting menace. The Committee suggests that trading in substandard and spurious drugs should be made a cognisable offence and the punishment should be deterrent, including not only heavy fines but also compulsory rigorous imprisonment ; the trader's licence should be cancelled and his name and address published.

The Committee found that out of 1,643 pharmaceutical factories in India nearly 93 per cent or 1,568 are small and insignificant. These have neither the technically qualified staff nor the

equipment to check the quality of either the raw materials or the finished product. The sooner they go out of existence the better for the country. The Committee recommends that in deserving cases a year's time may be given to wind up or to meet the requirements of the Drugs Act. The Committee lays down the minimum requirements of premises, equipment and qualified staff for a pharmaceutical factory.

Regarding raw materials of the industry the Committee suggests Government should take immediate steps to organise the cultivation of medicinal plants. For carrying out experimental work on their cultivation adequate grants should be made available by the Central and State Governments. The restriction imposed by certain State Governments in the interests of prohibition on the supply of alcohol to the industry should be removed. Methyl alcohol imported by pharmaceutical manufacturers are subject to the same restrictions and custom duties as potable spirits, when not used in bond or a denaturant not added to it. These restrictions should go.

The absence of facilities for collection and storage of animal glands restricts to negligible amounts the manufacture of hormones and glandular products. Modern slaughter houses with facilities for collection and storage of glands and organs should be established to start with in cities such as Bombay, Madras, Calcutta and Delhi. The collection and preservation of glands and organs should be supervised by qualified personnel and not left to the butchers as at present.

In order to overcome the defects in the operation of drug control existing at present, and to bring about a uniformity in the standard of products manufactured, the administration of drugs control should be centralised by bringing control on manufacture, sale and distribution, which is at present exercised by the State Drugs Controllers, under the Drugs Controller (India). This, the Committee feels, will help to bring about a uniform enforcement of the Drugs Act and better coordination in the administration of the Drugs Act and the Industries (Development and Regulation) Act.

Additional testing laboratories should be set up at the ports of entry of drugs. In every State or group of small States a well-equipped independent testing laboratory should be set up. The medical profession and the pharmaceutical industry should join together in setting up testing laboratories for the purpose of certifying the products made by the industry and thus create confidence among the public in the products manufactured by them.

Research in pharmacology in India is lagging behind chemical research. This is one of the reasons which prevents the development of chemical research in the field of drug industry. More adequate personnel, equipment and funds should be made available. It will also be necessary to train large numbers of chemists and biologists in pharmacology in addition to medical men. It should be made incumbent on manufacturers to spend a certain percentage of their profits on research. Research institutes in the country should keep a careful watch about the effects of new remedies that are being introduced into medical practice in rapid succession and make periodical reports.

It is necessary that a system of fair prices should be established and the system of price-cutting which leads to many malpractices including the sale of spurious and adulterated drugs should be stopped. An organisation representing both Government and trade should fix the consumer's prices of all drugs and medicaments.

The Committee points out that while stringent labelling provisions are laid down in the Drugs Rules, these unfortunately do not apply to advertisements in the lay press or medical journals or to literature supplied to doctors. This is a serious lacuna and should be rectified if blatant and even false claims often made by unscrupulous manufacturers are to be stopped. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, will, we trust, arm authority with adequate powers to deal with such advertisements.

The Committee recommends that the profession of pharmacy should be given a recognised place in society. The dispensing of drugs, the Committee holds, should ordinarily be done by pharmacists. A person should be allowed to enrol either as a medical practitioner or as a pharmacist but not as both. Doctors may, however, dispense drugs to their own patients. The Committee emphasises the need for a Central Institute of Pharmacy and separate State Institutes for imparting training in pharmacy.

The Committee stresses the need for better cooperation between the medical profession and the pharmaceutical industry. One suggestion, already dealt with is the testing and certification of drugs. The Committee also proposes an expert body for determining the essentiality of drugs and preparation of a list of standard combinations which should be allowed to be manufactured or imported. The Committee feels however that the preparation of a National Formulary should wait the completion of the Indian Pharmacopoeia. Our feeling in this respect is different. We are now flooded with a heavy influx of superfluous preparations. It is time that a list of essential drugs and combinations be drawn up by an expert body on which the

Indian Medical Association should have adequate representation, with a view to guiding production and imports. A panel of experts should report periodically on the list and such reports should be published for the guidance of all concerned.

Meanwhile we await Government's reaction to the Report.

PLANNING FOR THE FUTURE

The Central and the State Governments in their Five Year Plans have chalked out schemes for solving the medical and public health problems of the country and we as members of the medical profession look forward to their execution. In the present issue we present an article dealing with the future planning of the pharmaceutical industry in India. Drugs and pharmaceuticals are the weapons of the medical profession. It is, therefore, a serious problem of national interest that we ponder and ask ourselves the question "Are we self-sufficient so far as our needs for drugs and pharmaceuticals are concerned?" A glance at the mounting annual figures of imports of foreign drugs and pharmaceuticals will give us the answer.

In spite of a fairly large indigenous pharmaceutical industry imports have become necessary because many of the essential drugs are not being manufactured in this country. The reasons for this have been discussed in the paper referred to. During the periods of the wars we have had a measure of our helplessness; many patients were lost because some of the life-saving remedies were either not available or were beyond the reach of the average citizen. We had to pay heavily for this policy of looking to others for our essential needs. We therefore fully agree that "schemes for preparation of insulin, essential vitamins and amino acids, steroids, synthetic and chemotherapeutic agents, e.g., antimalarials, sulpha compounds, P.A.S., etc., plasma substitutes and, above all, antibiotics, the modern miracle drugs, should have priority in the future development programmes of the trade."

The Pharmaceutical Enquiry Committee in its report has discussed these problems in detail and has given their directives. Instead of running in the stereotyped pattern the people behind the trade should seriously analyse the situation and bring about the changes the industry needs.

The future possibilities of the trade are immense. With the increase of purchasing power of the people, with the raising of the standard of living, the demand for medicines is bound to go up in this country. Unless the pharmaceutical industry realises this and readjusts itself accordingly, increased consumption would mean increased imports—this is not sound economy.

At Trivandrum suggestions have been made about nationalisation of the drug industry. We do not know how this would help to solve the problems. If the manufacturers have faltered, let us extend a helping hand to them. To take away the management from their hands may not be the right thing at this stage. We would rather plead at this stage, for better direction for the industry and a better machinery for controlling the quality of the preparations.

Announcement

JOURNAL TO HAVE TWO VOLUMES A YEAR

The Journal of the Indian Medical Association while it had been a monthly had a single annual volume starting from the October issue each year and ending with the September issue of the next year.

With the publication of the Journal twice monthly and consequent increase in total bulk, a single annual volume becomes too unwieldy. We are therefore having two volumes a year. The first of such volumes (Vol. 24) ended with the last issue. Volume 25 starting with this issue will end with the issue of December 16, 1955. Subsequently fresh volumes will start with the first issues of January and July so as to fall in line with the general practice.

CURRENT MEDICAL LITERATURE

Blood Serum Reaction for Malignant Neoplasms

SEVA (*Yokohama M. Bull.*, **5** : 76, 1954) writes that in the present stage of medical science one of the prerequisite of checking cancer is an early diagnosis. Numerous cancer reactions have been discovered and published and the author presents a new reaction which has produced good results and can be performed easily by clinicians.

The Test—6 c.c. of blood is taken from the patient in the morning while on empty stomach and is placed quietly in the centrifuge-tube for 30 minutes and then separated to obtain a perfect centrifuge (3,000 r.p.m. for 10 minutes, the supernatant is sucked up and centrifuged again for 10 minutes). 1 c.c. of the serum thus obtained is ready for use. (The syringe and needle and the centrifuge-tube is washed carefully either with physiological saline solution or with 3·8 per cent sodium citrate solution before the test is performed).

The reagents are added in the order mentioned in the following table :

Reagents	Amount (cc.)	Remarks
1 Vitamin B_1 (5 mg. in 1 cc.)	1 drop	Motive of the use of vitamins lies in the literatures (6, 7) wherein I learnt the activating value of arginase, in cancer blood serum is lowered when $CUSO_4$ Vit. B_1 Vit. C are added. Vit. B_1 and C are added one and two drops respectively from two separate syringes with ⅚ mm. diameter needles attached. The mixture is kept at 38°C. Accurately for 40 minutes and other reagents are added in the order given only after cooling it from 15° to 20°C. Use of vitamins with accurate unit is desirable for the decision.
2 Vitamin C (50 mg. in 1 cc.)	2 drops	
3 Absolute alcohol	0·1	Used 1 cc. measuring pipette.
4 10 g/dl KOH solution	0·15	Used 1 cc. measuring pipette.
5 5 g/dl $CuSO_4$	0·1	Used 1 cc. measuring pipette. Contains 7·82 g. of 5 molecule hydrated $CuSO_4$ in 100 cc. of distilled water.
6 0·02 g/dl fuchsine solution	0·12	Used 1 cc. measuring pipette. Alkaline fuchsine.

Shake the mixture well for each reagent added. A control is always to be taken for each reaction.

REAGENTS USED :

5 mg. of vitamin B_1 in 1 cc. (in vial).
50 mg. of vitamin C in 1 cc. (in vial).
10 g/dl KOH solution.
5 g/dl $CuSO_4$ solution.
0·02 g/dl fuchsine solution.

Decision—Decision is made 20 to 30 minutes after the reaction by examining the colour tint of the blood serum against sunlight through frosted glass.

Purplish blue tint is considered negative, whereas that with a reddish color is positive. However it happens sometimes that the color is a little more reddish than in negative cases. Such cases are called "pseudopositive" which stand in the midway between the positive and negative cases.

Errors can be omitted by using control (healthy persons or noncancerous patients blood serum) at every time a test is performed. Serum of citrated blood as used in blood transfusion is considered in appropriate as control. Disadvantageous conditions caused by the high temperature in summer can be amended by cooling the reagents in 10° to 15°C. The temperature of the mixtures *in vitro* is to be held in 15° to 25°C. In winter when the temperature falls below 10°C, test should be performed in a room with a temperature of between 15° and 25°C. From my experiences it is concluded that hemolyzed serum and serum obtained within 30 hours of blood transfusion cannot be used.

Results—A resume of the results of the reaction tested cancerous and healthy people are given in the table below :

Classification	No. of cases	Positive	Pseudo-positive	Negative	Accuracy
Cases diagnosed definitely as "caner" by histopathological tests or (and) autopsy	122	112	5	5	91·80
Healthy people and other cases diagnosed definitely as "not cancer" by histopathological tests or (and) autopsy.	134	4	5	127	94·77

In taking the percentage of accuracy, the author considered pseudopositive as unfavorable. Those that proved to be positive or undetermined in serum samples of healthy people and non-cancer patients are believed to be either imperfect technique like slight haemolysis of mixing of blood cells, high temperature or use of poor-quality vitamins or serum obtained from blood extracted over 24 hours ago.

Drug-induced Diarrhoea

FRAME AND SHORT (*Lancet*, **1** : 434, 1955) write that fatal drug-resistant staphylococcal enterocolitis followed oxytetracycline (terramycin) therapy in a patient recovering from appendicitis and peritonitis. Less than

4·0 g. of oxytetracycline had been given when the symptoms first appeared, and despite the use of erythromycin and supportive therapy, he died about twenty-four hours later. A staphylococcus resistant to penicillin, chlortetracycline, and oxytetracyline was isolated from the throat, bowel, and blood, and from the viscera after death.

In treatment erythromycin and staphylococcal antitoxin should be given with supportive measures. This complication could perhaps be prevented by preoperative treatment of nasal carriers by topical application of an antibiotic.

Ganglion-Blocking Agents in Hypertensive Heart failure

SMITH AND FOWLER (*Lancet*, **1** : 417, 1958) give in the following lines the summary of their observations on prevention and treatment of hypertensive heart failure by ganglion-blocking agents :

A series of 114 patients under treatment with hexamethonium bromide for hypertension was studied, with special reference to the incidence and control of heart failure.

It was found that this treatment could not take the place of digitalis and mersalyl in the initial treatment of congestive heart failure, but by controlling the pressure it might prevent recurrence.

If left ventricular failure existed when the patient came under treatment it was generally relieved by hexamethonium bromide. In a few cases digitalis contributed to the control exerted by hexamethonium bromide. Dyspnoea lessened and cardiac asthma no longer occurred, and angina and gallop rhythm, if present, disappeared.

There was no death from heart failure, which is ordinarily the commonest termination of hypertensive heart-disease. Among the 14 deaths, strokes and uraemia were the main and nearly equal causes.

The authors consider that the main and attainable purpose of hexamethonium treatment is the prevention of left ventricular failure.

Side-effects may be formidable and demand relaxation of treatment; even so, when there is incomplete control of pressure, the main aim of preventing heart failure may still be achieved.

Results of Surgical Treatment of Carcinoma of the Lung

SELLORS (*Brit. M. J.*, **1** : 445, 1958) from an analysis of personal cases of cancer of the lung operated on between 1940 and 1950 observe :

Of a total of 680 thoracotomies, 446 were found suitable for excision—an operability rate of about two-thirds of the cases explored.

A follow-up to the end of 1953 gave for cases operated on prior to 1948 a survival rate of 34 per cent at the end of two years, 30 per cent at three years, 23·5 per cent at four years, and 21 per cent at five years. In the 1949-50 series 40 per cent were alive at the end of two years and 34 per cent at three years.

It is thought that there is some satisfaction that at least 20 per cent of these patients survived the five-year period. Moreover, the more recent cases suggest that this figure may be improved upon.

CURRENT TOPIC

QUARANTINE RESTRICTIONS AGAINST INDIA

Persons proceeding to U.S.S.R. from areas infected with cholera, plague, or smallpox are subject to quarantine for a period of 6 days in case of cholera, 9 days in case of plague and 14 days in case of smallpox even though they may be protected against the diseases by vaccination.

Persons proceeding to China are required to be in possession of international certificate of vaccination against cholera and smallpox.

Persons arriving from cholera infected areas and who are carrying valid international cholera vaccination certificates will be placed under surveillance for an appropriate period in case they arrive within 5 days of the date of their departure from cholera infected areas. Passengers who are not in possession of valid certificates will be placed in isolation until they have completed a period of 5 days from the date of their departure from the infected areas, and in addition will be subject to a stool test.

(i) *Smallpox and Cholera* : In addition to countries which have imposed specific restrictions against smallpox or cholera or both many other foreign countries require vaccination certificates in respect of smallpox and cholera from passengers from India. Passengers going abroad should accordingly get themselves vaccinated against these diseases and obtain appropriate certificates.

The certificates should be in the international form as given in the International Sanitary Regulations authenticated by the impressions of the "approved stamps". This stamp is held by the Directorate; Deputy and Assistant Directors of Public Health, Chief Medical Officer; Administrative Medical Officers; District Medical Officers of Health; Civil Surgeons; Assistant Surgeons; Medical Officers of Health, Municipalities, Corporations and Local Bodies and the Medical Officers in charge of all Presidents and Secretaries of the Local branches of the Indian Medical Association, etc.

The new forms of International Vaccination Certificates have been printed which Vaccinating authorities may obtain from the Manager of Publications, Civil Lines, Delhi, on payment of one anna per booklet.

The international accepted period of validity of cholera and smallpox vaccination certificates are as follows :

Cholera Certificates : The validity of this certificate shall extend for a period of six months, beginning six days after the first injection of the vaccine or, in the event of revaccination within such period of six months, on the date of that revaccination. However in the case of a Haj Pilgrim, the certificate shall indicate that two injections have been given at an interval of seven days and its validity shall commence from the date of the second injection.

Smallpox : The validity of this certificate shall extend for a period of three years, beginning eight days after the date of a successful primary vaccination, or, in the event of revaccination, of the date thereof.

The validity authorities have prescribed their own forms of smallpox and cholera vaccination certificates

for issue to the active members of the Armed Forces in accordance with the International Sanitary Regulations. Such certificates will bear the Military Official Stamp, instead of the 'approved stamp'.

(ii) *Plague* : Plague vaccination certificate is not prescribed in international practice and there is no prescribed form of such certificate, when, however, plague vaccination certificate is demanded by any country the immunisation against plague should be done by giving two injections of the vaccine with an interval of one week between the two injections. The validity of this certificate shall extend for a period of 8 months, beginning 10 days after the first injection.

(iii) *Typhus* : Typhus inoculation certificates are not prescribed in international quarantine and are not required. Travellers to Ethiopia, Korea and Tanganyika are, however, advised in their own interest to get themselves immunised against typhus.

(iv) *Typhoid and Para Typhoid* : Passengers going to French Settlements in Oceania, Korea, Indonesia, Netherland, New Guinea, Belgian Congo, Ruandi Urundi, Somalia (Italian Administration), Tanganyika, Colombia, Panama Canal Zone, New Caledonia and United States Trust Territories of Pacific Islands are advised in their own interest to be in possession of vaccination certificates form for this certificate. Immigrants to American Samoa, Cambodia and Israel are required to be in possession of certificates of vaccination against Typhoid fevers.

(v) *Yellow Fever* : Yellow Fever vaccination certificates are not normally required from travellers from India except by a few African countries. As the storage and Administration of Yellow Fever vaccine is controlled by the Government of India, this vaccine is not available to private medical practitioners, or to the general public. In India yellow fever vaccination is carried out and certificates issued at the centres by authorities mentioned below :

(*i*) Saffkine Institute, Bombay, (*ii*) All-India Institute of Hygiene and Public Health, Calcutta, (*iii*) King Institute of Preventive Medicine, Guindy, Madras, (*iv*) Central Research Institute, Kasauli, (*v*) Airport Health Officer, Bombay Airport, Bombay 29, (*vi*) The Delhi State Public Health Laboratory, Connaught Place, New Delhi, (*vii*) The Chief Medical Officer, Porbandar State, (*viii*) Nawanagar State Irwin Hospital, Jamnagar.

The validity of Yellow Fever vaccination certificates shall commence :

(*i*) 12 days after vaccination, (*a*) if the vaccination is carried out in Yellow Fever endemic area ; or (*b*) if the vaccination is carried out in a non-endemic yellow fever area and the person enters a yellow fever endemic area within ten days of vaccination.

or (*ii*) Ten days after validity of the certificates shall extend for a period of six years. If revaccination is done within validity period of six years the certificate shall be valid from the date of revaccination.

The Yellow Fever vaccination certificates will bear the official stamp of the vaccination centre. The "approved stamp" will not be used on this certificate.—(*Issued by the Director General of Health Services, Government of India*).

NOTES AND NEWS

Awards for Published Medical Researches

Six prizes of about Rs. 300 each will be awarded annually for six best published research works in any subject of medical science in general, including clinical research, by the Indian Council of Medical Research out of a donation of Rs. 50,000 given for this purpose by Lieut.-Colonel Amir Chand, former Principal, Lady Hardinge Medical College, New Delhi. The Council has constituted a 'Col. Amir Chand Trust' for the administration and management of the Fund. The selection of prize winning entries will be made by a selection board. The name of the first winners of the prize will be announced at the annual meeting of the scientific advisory board and the advisory committees of the Indian Council of Medical Research to be held at Nagpur in November-December, 1955.

Unregistered Vaidyas

The Government of India has appointed a committee with Mr. D. T. Dave, Health Minister of Saurashtra, as chairman, to formulate a uniform policy in respect of the education and regulation of the practice of unregistered vaidyas, hakims and homoeopaths.

The Health Ministers of Bombay, West Bengal, Hyderabad and Travancore-Cochin will be the members of the committee.

The Director of Health Services, Punjab, and the Director of the Central Institute of Research in Indigenous Systems of Medicine, Jamnagar, will serve as secretary and joint secretary of the committee, respectively.

The committee has been asked to submit its report to the Government of India within six months.

All-India Ophthalmological Conference

Srimati M. Chandrasekhar, while inaugurating the Sixteenth All-India Ophthalmological Conference, organised by the All-India Ophthalmological Society, said that the ophthalmic problem cannot be dissociated from other health problems, and that it must find its proper place as part of the general public health programme for the people.

The problem of the blind is partly one of medical measures and partly one of education and rehabilitation so as to enable the afflicted persons to become, as far as may be possible, useful members of society. The Health and the Education Departments of Governments will have to work together to develop adequate measures and to promote their execution as a joint effort with the closest possible degree of co-operation. Such collaboration is desirable and necessary in the interests of the blind.

Anti-Diphtheria Measures on Mass Scale

A scheme for the immunisation of children against diphtheria on a mass scale was accepted in principle at the weekly meeting of the Delhi Municipal Committee on 11-8-55.

Since the Committee had no funds to undertake the work, it was decided that the Government be requested to make a special grant of Rs. 2,00,000 a year for the purpose. It was further decided that in the meantime the Medical Officer of Health should put up proposals for taking up the work in hand immediately with Rs. 20,000 provided for in the budget.

During the discussion on anti-diphtheria measures, some members suggested that in addition to preventive measures, efforts should also be made to eradicate the main cause of this highly infectious disease. On the basis of statistics available, it was pointed out at the meeting that the incidence of diphtheria cases in the city was on the increase. In 1947-48, the number of cases was 65, while during last year the number shot up to 712. During the last seven years, the incidence of cases had been steadily going up. According to the data collected in this connection, it was apprehended that the incidence of the disease would continue to rise in the absence of any proper preventive measures. In view of this, the Director of Health Services had stressed the need for protecting children below the age of 10 against the disease as quickly as possible.

Health Measures in N.-E.F.A.

Continuous efforts made by the North-East Frontier Agency Administration have brought the benefits of modern medicine within the reach of the needy and sick tribal people.

During 1953-54, 75,000 cases of malaria were treated. Anti-malaria units of the Agency sprayed 20,000 houses with DDT and distributed pills.

In February, they surveyed 81 villages covering a population of 18,180. One anti-malaria unit was opened at Kiphire in the Tuensang Frontier Division.

Seven hospitals and dispensaries were opened during 1953-54 raising the total bed capacity to 252. Two 11-bed hospitals started functioning in the Lohit Frontier Division in February.

One midwife has been posted at Dirang-dzong, in the Kameng Frontier Division, for opening a child health centre there. Another maternity and child health centre was opened at Mon, in the Tuensang Frontier Division.

CORRESPONDENCE

The Editor is not responsible for any views expressed by correspondents

Effective Use of Terramycin in Combating Streptomycin-Resistant Organisms in Vaccine Lymph (Calf Lymph) a, b.

SIR,—The effectiveness of streptomycin in the bacterial purification of vaccine lymph has been communicated by me already elsewhere (Krishnamurthy, 1950a, 1950b). Based on these findings, a simple technique of preparation of vaccine lymph by spraying streptomycin solution externally over the vaccinated surface of the calf has been evolved and adopted by me at the Government Vaccine Institute, Bangalore 2.

The ease with which bacteria become resistant to streptomycin is well known (Garrod, 1951). Similar development of resistant strains in the calf lymph was naturally anticipated. In the early stages, when streptomycin was first employed for the bacterial reduction of vaccine lymph, no streptomycin-resistant colonies were encountered. A little later, lymph samples from about 17 per cent of the calves treated with streptomycin showed resistant colonies which rose to about 40 per cent in due course. This included some colonies of haemolytic type of staphylococcus which rendered the vaccine lymph unsuitable for human use.

The value of oxytetracycline in overcoming the streptomycin resistant colonies in the vaccine lymph was then studied. Spraying of oxytetracycline (10 mg./ml.) in combination with streptomycin (10 mg./ml.) in sterile 50 per cent glycerol, over the vaccinated surface of the animal twice a day for five days was found to reduce bacterial contamination to the required extent consistently in all the lymph samples. Mere streptomycin (10 mg.—20 mg./ml.) spraying gave resistant colonies in about 40 per cent of the lymph samples.

10 mg./ml. of oxytetracycline seems to be optimal for use with streptomycin as a lesser concentration of the antibiotic (5 mg./ml.) failed to prevent the emergence of the streptomycin-resistant colonies completely.

Oxytetracycline employed in the above manner, does not appear to have any action on the vaccinia virus as no loss of potency was observed in the treated lymphs. The viral titration was done on the skin of the rabbit by the scarification technique. On the basis of these findings, oxytetracycline could be employed in combination with streptomycin to overcome the streptomycin-resistant strains in Vaccine Institutes which use streptomycin for the routine bacterial purification of vaccine lymph. This also works out to be economical as vaccines so treated could be diluted about 20 or more times in view of their high potency.

I wish to express my grateful thanks to Dr. T. Chandrasekharaiya, Director of Public Health in Mysore, Bangalore, for his encouragement and support and Dr. S. Seshagiri Rau, Deputy Director of Public Health, for his stimulating interest in this work.

I am indebted to Messrs. Pfizer & Co., for a liberal supply of their oxytetracycline (Terramycin) and streptomycin sulphate for these experiments. I am etc.,

Government Vaccine Institute,
Bangalore.

V. N. KRISHNAMURTHY, M.D.

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III RAJPUTANA MEDICAL CONFERENCE, JODHPUR

The 3rd Rajputana Medical Conference was held on the 5th, 6th and 7th December, 1954. Dr. D. G. Ojha was the Chairman of the Reception Committee. Sri Mohanlalji Sukhadia, the Chief Minister of Rajasthan inaugurated the conference and Dr. R. S. Heilig presided over it. Sri Kumbharam Arya, Health Minister, Rajasthan opened the Scientific Exhibition and Sreemati Kamla Beniwal, Deputy Health Minister presented the prizes to women of the baby show. A Symposium on Medical Education was held after the general sessions of the conference and it was presided over by Dr. S. C. Sen, the president of the Indian Medical Association. About 500 medical men from all parts of India attended the function. Some of the Ministers of Rajasthan were also present.

Sri Mohanlalji Sukhadia, inaugurating the conference wanted medical facilities to be made available in the rural areas and to the poor at cheap rates. He assured that the Government would consider the proposal of another medical college in Rajasthan as also the grievances of compounders and nurses, the question of discriminations in classifications and State aid for increased medical facilities. He appealed to the medical men to devise measures to check the spread of diseases like malaria in the villages. The situation in his opinion would not improve if medical men did not serve the rural areas.

Dr. Ojha, the Chairman of the Reception Committee accorded a hearty welcome to the delegates and guests. In his address he pleaded for the expansion of compulsory health insurance scheme, at present limited to the employees in industrial cities, in rural areas also. He believed that even if it were on a voluntary basis, the people in the villages would go in for it wholeheartedly because better health meant more output of work and more prosperity and welfare.

Dr. R. B. Heilig in course of his address, said,

"As a profession we are at more than one crossroad at the present time. We have to face the revolution brought about by Health Insurance, public or private. Having worked in Vienna, the cradle of national health insurance, for almost twenty years, fifteen of them in closest connection with health insurance, I can say that if properly organised it has got its good sides, whereas there are also many possibilities to handle it fully to the disadvantage of the medical man. If it is run on strictly bureaucratic lines, with non-medical people in sole charge of the administration and taking all major decisions, untouched by any medical knowledge or public health experience it will become better for us to become chowkidars than doctors serving health insurance projects. Such a development which is not at all improbable, civil servants being not only omnipotent but also omnipresent and omniscient, can be avoided only if we close our ranks, joining the Indian Medical Association like one man. This would strengthen the hands of our representatives, particularly the President, so that he can speak and negotiate on behalf of the united medical profession of India without the faintest possibility of anybody saying that he represents only a fraction of our brethren. All other interests of doctors in every country that calls itself civilised are being subordinated to the one overriding aim of creating and keeping strong as the collective representative of the profession a closely knit national medical association, membership of which is the natural hallmark of every qualified practitioner of scientific medicine. You all know that it would be unthinkable for a registered practitioner or specialist in the U.K., the U.S.A. or any continental country outside the Iron Curtain not to be a member of the B.M.A., A.M.A. etc., inspite of compulsory contributions incomparably higher than ours, reaching upto 10 per cent of the net income as in a tiny country like Israel where,

Dr. R. B. Heilig, the President of the Conference

inspite of an incredibly high standard of public health services, doctors have to fight hard for their rights with the all powerful trade unions, that are their employers.

Summing up *point one* of this address, you will all agree with me that at the present moment where the future of all of us is in the balance, depending on our position in the soon all-comprising, all dominating national health insurance, it is the first duty of every medical man and woman to strengthen the hands of the I.M.A. by joining it and the equally prime duty of every one of us who is a member already to make the others join, who are outside still.

The next point I want to discuss and one that can be achieved only by a powerful negotiator on our behalf is that the vast majority of the medical personel working for health insurance organisations should do so *part-time*. This view is based on years of experience in Vienna where every employee from labourer to manager, from peon to secretary to government, was entitled to free medical aid outside and inside hospitals, whereas employers, lawyers etc. had their private health insurance institutions which reimbursed their members' expenditure for doctor, hospital etc. In all these organisations only chief medical officers whose duties were mainly of an administrative nature were full-time appointed while all the practitioners and specialists had fixed consulting hours for their panel patients and were free for private practice all the rest of the time, apart, of course, from emergency calls to which they had to attend at any time. The fact that every day some hours were devoted to private practice had the most beneficial influence upon the mental condition and attitude of all medical people who were reminded whenever they attended on private patients that medicine is not limited by rules and regulations of panel institutions, that it is like a living organism, whether the civilians who were supervising health insurance in the Health Ministry and the politicians who were actually running the various insurance institutions, took notice of it or not. Apart from the necessity to keep pace with actual progress, the continuous contact with private patients helps also the practitioner to preserve the doctor's human touch and to avoid the development of officiousness, with the outlook which is concerned only with rules to which the case must conform and not with the unlimited variability of human life and suffering. My *second point* is, therefore, let us close our ranks, let us build up a strong Association so as to convince the powers who are fixing the structure of the impending health insurance organisation, that both patients and doctors, are standing to benefit from part-time work of panel practitioners.

Another set of problems that claim our attention is the increasing preference shown by state governments for indigenous systems of medicine over scientific medicine. It does not help to emphasize the fact that India is the only country in the world that not only permits but actively promotes the practising of the relics of hoary past systems which are characterised by the complete and unmitigated absence of any knowledge of preventive medicine and of surgery. As beyond any doubt modern public health measures consist mainly in the prevention of disease, it should be clear to every unbiased individual that the ancient indigenous systems simply can not deliver the goods. But even if these worshippers of the past whose judgment is not influenced by any rational thinking concede that inoculation, vaccination and mass-X-ray surveys might have to be borrowed from the so-called Western medicine, they will insist that non-surgical curative medicine shall be carried out, partly at least on indigenous lines. It is hardly possible to explain to a medical visitor from an advanced country how such an attitude can be maintained by people responsible for the health of the masses in the era of chemotherapy and antibiotics when even China, that boasts of the highest developed indigenous system of medicine, has decided to discontinue its practical application. And yet, it is undeniable that with the exception of the Centre, almost every government in India favours Ayurvedic medicine by founding new colleges, hospitals and dispensaries for teaching and practising indigenous systems. It is no use to protest against such trends, democratic governments are bound to carry out the wishes of the majority while we have the right and the duty to investigate why such a large number of laymen do prefer such outdated methods of treatment to the truly dazzling achievements of scientific medicine.

The answer seems fairly obvious and I do not think that sentimental reasons have much influence with the man in the street or the businessman who choses a vaid as his medical adviser. How have they formed their opinion about modern medicine? For generations the authorities have given in the state dispensaries free demonstrations of what can be expected from Western medicine on the curative side. Need I tell you how much of the amazing achievements of scientific medicine are offered by government dispensaries? Look at the formulas of the time dishonoured stock mixtures, at their treatment for anaemias, for tuberculosis, for dysenteries and urinary tract infections, for infantile diarrhoea or even for pneumonia. I do not mean what the M.O. might prescribe, I mean what he can hand out for oral or parenteral treatment on the spot in the village dispensary at government expenses and I ask you whether this approved treatment is likely to be so much more effective than the vaid's treatment who is giving liver and penicillin injections, sulphadrugs and broad spectrum antibiotics on a scale of which the Raj doctor cannot dream; in addition, an experienced vaid has got at his disposal a large amount of drugs that, with the exception of quinine and digitalis, are as effective as those provided by our pharmacopoea before 1894, when Behring discovered anti-diphtheria serum, considering always that ayurveda does not provide for prevention of small-pox or rabies, diphtheria or tetanus, typhoid, cholera or plague, tuberculosis or whooping cough, all preventable diseases which, with the exception of the last two, have been completely eradicated in every normally developed country, advanced only in comparison with countries like ours. The incredible backwardness of our statedispensed medicine is the explanation of the success of indigenous systems, the practitioners of which incorporate into their armamentarium whatever they find effective of Western medical discoveries. *Point three* of our demands I would formulate as the most urgent necessity to enable the medical officers of government dispensaries to treat their patients according to the present standard of scientific medicine and not by a formulary that has been antiquated 50 years ago.

Should such a suggestion be accepted and carried out on a substantive scale, the consequences might be deleterious. What with the W.H.O. having taught our public health services how to prevent malaria on a large scale and having just earmarked some 4·5m. for the introduction of sanitary engineering in S. E. Asia so that typhoid, dysenteries and cholera will lose their grip on our people, if in addition our government should provide up-to-date treatment to the masses, Yama will join the army of unemployed, millions of lives would be saved to make our food problem insoluble even for a wizzard. The facts which are dominating our food and population problems are frightfully simple. The world food production increases by about one per cent annually while the world population increases by about the same percentage. If the food produced all over the world could be distributed equally, the present per capita consumption could be just maintained. In reality, however, the distribution is not at all equal. Whoever can pay more gets a larger share so that the wealthy or advanced nations whose population amounts to about one-fifth of the world population consume about one half of the production increase, leaving a slowly but steadily increasing gap between food requirements and food supply; very few responsible economist doubt nowadays that Malthus was essentially right. The last year or two these facts have been somewhat obscured by bumper crops of rice in India, Burma and Thailand and excellent wheat crops elsewhere. But you have only to remember that our population increases by more than one per cent, that is at present 36 to 40 lakhs every year to realise that only a general, radical birth restriction can save us from national ruin brought about by increasingly deficient food supply. An example of what is in store for us happened in British Guiana quite recently when systematic large scale D.D.T. spraying reduced malaria and malaria caused mortality to such an extent that the per capita available food was reduced from 2,000 to 1,600 calories.

Let us not be misled by the official jubilation over the grain targets set by the Five Year Plan being reached; these targets have been underestimates, fixed lower even than the prewar per capita food intake. Let us not forget that our average caloric intake is still about ten per cent below that of 1939 and that of proteins the second lowest in the world. Inspite of Sindri, Japanese method of rice cultivation etc., our aim to raise the living standard and through it the efficiency of our masses to something approaching those of developed countries cannot be achieved if our population continues to increase at the present rate. You have only to look into the last census report to see how soon our population will reach a point beyond which the country's food producing capacity cannot be stretched so that nothing but misery can be expected for the coming generations. It is our, the doctors', sacred duty to prevent such a development. Nobody but the doctor can persuade people to plan the size of their families, nobody else can tell them how to do it and only we can convince them that male sterilization is perfectly harmless, particularly as far as potency is concerned. In fact the once famous Steinach operation for increasing sex power consisted in nothing but vasectomy, the idea being that prevention of external secretion should stimulate endocrine output.

According to the estimates of the census report the main difficulty in balancing our food resources and our frantically growing population is created by the large number of families with more than three children, no other country reaches the same proportion of families with four, five and more children. Our task, therefore, is simply to persuade people to stop procreation after the third child. This should not prove impossible, particularly if we can convince that male sterilization is harmless, apart from being the only method that permits of mass application. I think that propagation of birth control so as to limit the family size to three children is one of the main tasks and probably the most urgent one that every member of the medical profession in India has to fulfill as a citizen of this great country.

I have put before you four propositions, a four point programme so to speak, dealing first with means how to make our voice heard during the critical period of health insurance organisation, secondly with a way to improve the lot of patient and doctor in the health insurance institutions, thirdly with methods to make better use of the curative capacity of scientific medicine and, finally, I pointed out the overriding necessity to advise our people on means of family restriction. If we achieve even partial success in these directions by the end of this term, the existence of the Rajputana Provincial Branch, I.M.A., has been justified.

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The following resolutions were passed at the conference :

(1) Resolved that Rajputana Provincial Branch of the Indian Medical Association request the Government of Rajasthan that all the medical officers in the Rajasthan Government service and the members of the Indian Medical Association be given free treatment and cottage ward facilities as is provided for the government servants drawing a salary of Rs. 250/- and over.

(2) The Rajputana Provincial Branch of Indian Medical Association recommends to the government of Rajasthan that the remuneration granted to the medical officers of the Rajasthan government servants should be at par with the rules of the Central government employees.

(3) The Rajputana Provincial Branch of Indian Medical Association recommends to the government of Rajasthan that registered medical practitioner whether in government service or in private practice be authorised to issue medical certificate irrespective of their class or qualifications.

(4) The Rajputana Provincial Branch of Indian Medical Assoliation urges the government of Rajasthan that in the best interest of the administration and fairness to the medical practitioner the government should standardise the hospitals as regards the alliotment of the specialists cadre and thereafter lay down definite criteria like basic qualifications, specialists qualifications, experience and seniority etc. for appointing the doctors in respective cadres on these criteria alone.

It further urges that one uniform specialist cadre be kept and distinction in junior and senior specialist cadre be avoided.

BRANCH NOTES

ALWAR BRANCH—A meeting of the branch was held on 13-4-55. Dr. R. N. Sachdeva presided. Dr. Gouri Shanker spoke on early "Tuberculosis, Leprosy and Oriental Sore", Dr. P. N. Mathur on his recent experience of Camp Surgery.

ANANTAPUR BRANCH—A meeting of the branch was held on 30-4-55 with Dr. Ramanath in the chair. Dr. V. K. Rajaram read a thesis on "Common Disorders of Infancy and Childhood in general practice."

BANGALURE BRANCH—On 14-4-55 a meeting of the Executive Committee was held under the presidentship of Dr. M. Sirsi, President of the Branch. Circulars received from the Centre regarding proposed amendment to Rules of I.M.A. were discussed. Further it was resolved to request all the members of the Branch to contribute towards the purchase of a 16 m.m. Sound Projector.

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On 23-4-55 talks and discussions on 'Family Planning in Practice' was held. Dr. H. Krishna Rao gave a talk explaining the advantages and disadvantages of various methods in practice. Drs. C. V. Natarajan, P. Krishna Rao, T. K. Dayalu and Ratnamma Isac took part in the discussion. Dr. M. Sirsi presided. Before the commencement of the meeting, a condolence resolution on the sad demise of Mrs. Mary Langford Taylor, President of the Bangalore Branch of Family Planning Society of India, was passed.

BELGHARIA BRANCH—A meeting of the branch was held on 24-4-55. Dr. S. K. Nandy spoke on "Tuberculosis" with demonstrations by X-ray plates. Dr. B. N. Chatterjee also spoke on the subject. Dr. A. C. Mitra (Radiologist) spoke about "Radiology and the Methods of Diagnosis". Thirty members were present.

COCHIN BRANCH—On 16-10-54, an ordinary meeting was held with demonstration of clinical cases by Capt. M. A. Urumese of General Hospital, Ernakulam.

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On 22-10-54 a special meeting was held with demonstration of 2 talkie films viz., 'Aureomycin and Polvite'.

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On 27-11-54 an ordinary meeting was held. Dr. S. B. Rao spoke on 'The Birth of a New Drug' and Sri V. R. Sastry on 'The Problem of our Fallen Sisters'.

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On 21-12-54 an ordinary meeting was held. Dr. C. C. Karunakaran, President, Travancore-Cochin medical Association spoke on 'Employees State Insurance'.

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On 12-1-55 an ordinary meeting was held. Prof. R. Rothlin, Director, Pharmacological Section, M/s. Sandoz, Ltd., Basle (Switzerland) spoke on 'Modern Conception of the Autonomic Nervous System and its Clinical Importance'.

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On 28-1-55 a special Lunch meeting was held to give a most befitting welcome to Dr. S. C. Sen, President, Indian Medical Association.

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On 11-2-55 an ordinary meeting was held. Dr. George Coelho, Hony. Pediatrician, Byramjee Jejeebhoy Hospital for the Children, Bombay, spoke on 'Convulsions in Children'.

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On 10-3-55 an ordinary meeting was held. Clinical cases were demonstrated by Dr. P. K. Raghava Warrier.

GHUGUDANGA BRANCH—A meeting of the branch was held on 10-4-55 with Dr. S. Sarker in the chair. Ten members were present. At the suggestion of Dr. A. K. Bose and Dr. J. Mojumdar, the president and secretary of Bengal Provincial Branch, it was decided to call a general meeting of the medical practitioners to find out ways and means for the betterment of the branch.

JAGATDAL BRANCH—A meeting of the branch was held on 5-4-55 when the members congratulated Dr. S. C. Sirkar and Dr. P. Sinha on their success at the municipal election.

JAMSHEDPUR BRANCH—The annual general meeting was held on 12-4-55. Sixty-two members were present. Office bearers were elected with Dr. D. N. Mookerji as president and Dr. R. C. Tarapore as hony. general secretary.

KALYANI BRANCH—A meeting of the branch was held on 22-4-55 with Dr. B. Mukherji in the chair. Dr. K. R. Adhikari read a paper on "Toxic effects of P.A.S." with a few case reports.

MUZAFFARNAGAR BRANCH—A meeting of the branch was held on 20-3-55, with Dr. Vishnu Datt in the chair. Mrs. L. Madan gave a complete survey of Medical Education, Hospitals, Members of the Profession and allied subjects in U.S.S.R.

NIZAMABAD BRANCH—A meeting of the branch was held on 24-4-55 with Dr. L. R. Deshpande, Civil Surgeon, in the chair. Dr. K. V. Subramanyam, medical officer, Bodhan, spoke on "Minor Maladies and the Treatment".

POONA BRANCH—The Poona Branch of the I.M.A. intends to celebrate its Silver Jubilee this year on 1st June 1955, and in this connection has arranged to hold a Poona Medical Congress where Scientific Papers will be read by eminent specialists from Bombay, Miraj and Poona itself. The programme is to be spread over for 3 days.

PORBANDAR BRANCH—A meeting of the branch was held on 27-3-55 with Dr. H. H. Chavda in the chair. Thirteen members were present. The Government of Saurashtra was asked to recognise the Indian Medical Association as the official month piece of qualified medical practitioners and this association should be consulted in all matters relating to qualified medical practitioners. Dr. J. P. Sthanke read a paper on "Vitamin C", Dr. P. B. Pandya on "Herpes Zoster". A number of films were demonstrated.

SALEM BRANCH—In a meeting of the branch, held on 10-3-55, Dr. V. Hariharan, Supervising Public Health Officer, B.C.G. Campaign, Madras, spoke on "The Role of B.C.G. in the Control of Tuberculosis.

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The annual meeting of the branch was held on 7-4-55 with Dr. S. Krishnamoorthy Rao in the chair. New Office bearers were elected with Dr. S. Krishnamoorthy Rao as president and Dr. V. Raghavendra Rao as hony. secretary. Dr. P. Arunachalam, Retd. Director of Medical Services, spoke on "Cortisones in General Practice."

TENALI BRANCH—A meeting of the branch was held on 27-2-55 with Maj. K. Vullakki in the chair. Dr. Kodamaramaiah of Guntur Medical College spoke on Nephritis and its Management.

TIRUCHY BRANCH—Clinical meetings were held on the following dates with Dr. N. C. Subramanyam in the chair. On 15-2-55, the meeting condoled the tragic and untimely death of Dr. M. V. Sundaresan, a member of the branch. Thereafter Dr. M. D. Ananthachary read a paper on the Problems of Typhoid; on 17-2-55, Dr. A. T. John on "The Role of Antibiotics in pediatrics with special reference to infections in early infancy"; on 18-2-55 Dr. P. Natesan on the History of Syphilis; on 19-2-55, Dr. C. Raghavachary on Acute Intestinal Obstruction; on 21-2-55, Dr. N. Chandrasekaran on Spinal Anaesthesia; on 22-2-55, Dr. C. Sathyanarayana on Hoarseness Cancer of Larynx and M. Natarajan on Backache; also a film on Operation Laryngectomy was shown by Dr. C. Sathyanarayana; on 25-2-55 Dr. M. K. Krishna Menon spoke on the Third Stage of Labour.

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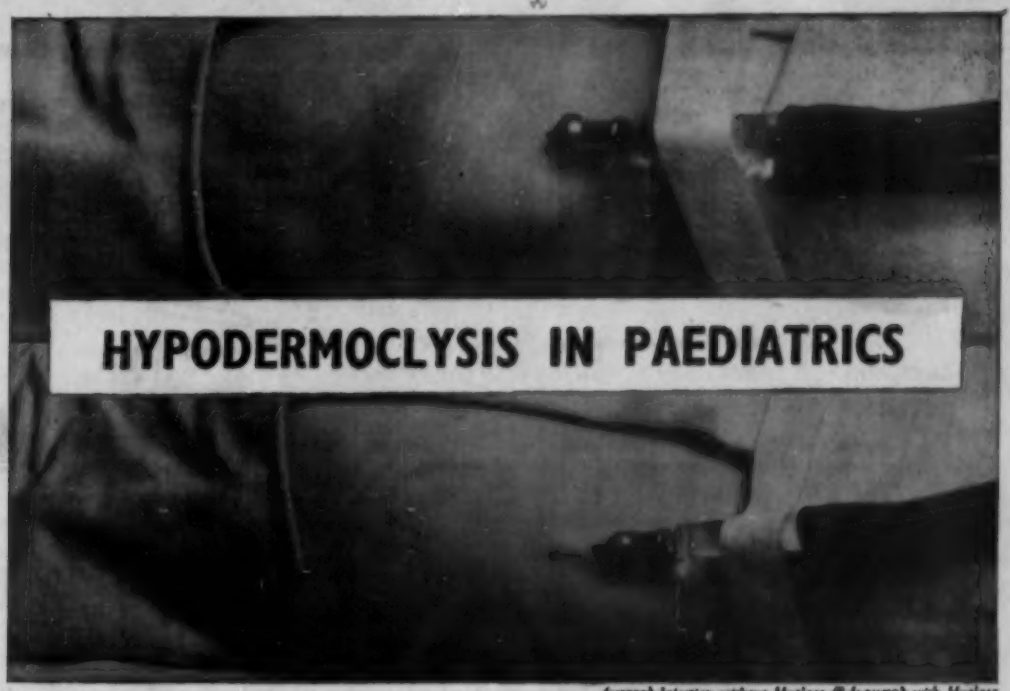
A meeting of the branch was held on 3-4-55 to meet Sri A. B. Shetty, Minister for Public Health. Fifty members were present.

TIRUNELVELI BRANCH—A meeting of the branch was held on 26-2-55. It was proposed to look into the feasibility of the construction of a building for the association. A few clinical cases were demonstrated by the D.M.O. and Dr. K. Ramachandra Naidu, Dr. S. Kameswaram spoke on the subject of "E. N. T. diseases in general practice."

DR. S. C. SEN, THE PRESIDENT OF THE INDIAN MEDICAL ASSOCIATION AND DR. A. P. MITTRA, THE HONY. GENERAL SECRETARY WITH THE MEMBERS OF THE MUZAFFARNAGAR BRANCH, I.M.A.



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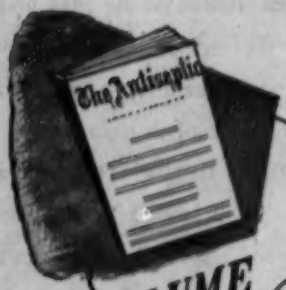

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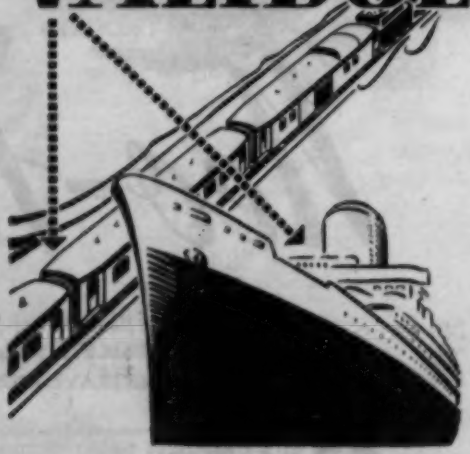

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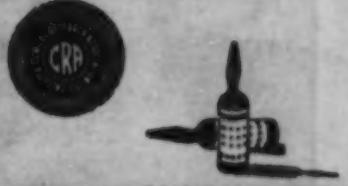

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